

US3162003 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:23:27

All time stamps listed in this document are displayed in GMT

US3162003

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 21:04:07

Generated On: 09 Jun 2021 15:23:27

Participant ID

US3162003

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

US3162003

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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

Visit date (dd MMM yyyy)	27 JUL 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3162003

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 21:04:10

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3162003

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 21:04:10

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Condition	LEFT WRIST FRACTURE
Start date (dd MMM yyyy)	UN OCT 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAR 2012
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2011
Start Year (derived)	2011
Stop Month and Year (derived)	MAR 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 21:04:10

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Condition	CERVICAL DISC DISEASE
Start date (dd MMM yyyy)	UN DEC 2008
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)	DEC 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Condition	MENOPAUSAL
Start date (dd MMM yyyy)	UN JUL 1988
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)	JUL 1988
Start Year (derived)	1988
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Condition	PREVIOUS SMOKER
Start date (dd MMM yyyy)	UN UNK 1961
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1961
Start Year (derived)	1961
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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)	13:12 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 13:12
Height (xxx.x)	62 in
Weight (xxx.x)	164 lb
BMI (xxx.x)	30.05871 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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.

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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 JUL 1988

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:04:10

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:04:10

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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

Visit date (dd MMM yyyy)	27 JUL 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3162003

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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

What was the participant's randomization number? 184039

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 21:04:10

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 JUL 2020
Time of assessment (00:00-23:59)	13:12 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 13:12
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 JUL 2020
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 14:55
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3162003

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3162003

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 14:19 (24 HR)

Treatment Date and Time (derived) 27 JUL 2020 14:19

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

US3162003

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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)	14:12 (24 HR)
Collection date and time (derived)	27 JUL 2020 14:12

US3162003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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	14:16	27 JUL 2020 14:16
Nasopharyngeal Swab 2	No		

US3162003

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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 14:39

PC Close Date & Time

27 JUL 2020 17:09

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °F

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

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

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

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

PC Time Stamp 27 JUL 2020 18:07

PC Open Date & Time 27 JUL 2020 18:04

PC Close Date & Time 28 JUL 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

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

28 JUL 2020 12:02

PC Open Date & Time

28 JUL 2020 12:00

PC Close Date & Time

29 JUL 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 JUL 2020 12:03

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 JUL 2020 12:02

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 17:37

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

01 AUG 2020 17:39

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 17:15

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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 14:39

PC Close Date & Time

27 JUL 2020 17:09

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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 18:05

PC Open Date & Time

27 JUL 2020 18:04

PC Close Date & Time

28 JUL 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

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

28 JUL 2020 12:03

PC Open Date & Time

28 JUL 2020 12:00

PC Close Date & Time

29 JUL 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

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 12:02

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

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

30 JUL 2020 12:03

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

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

31 JUL 2020 17:38

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 17:40

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 17:16

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

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

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

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 14:39

PC Close Date & Time

27 JUL 2020 17:09

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

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

No ☒

Yes ☐

PC Time stamp	27 JUL 2020 18:08
PC Open Date & Time	27 JUL 2020 18:04
PC Close Date & Time	28 JUL 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

Yes <input type="checkbox"/>	
PC Time stamp	28 JUL 2020 12:04
PC Open Date & Time	28 JUL 2020 12:00
PC Close Date & Time	29 JUL 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

Yes <input type="checkbox"/>	
PC Time stamp	29 JUL 2020 12:01
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 12:03
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 17:39
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2940

EAB) (1725)

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 17:40
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 2940

EAB) (1725)

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 17:16
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3162003

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3162003

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162003

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162003

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162003

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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

Visit date (dd MMM yyyy)	24 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	12:59 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 12:59
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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)	14:49 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 14:49
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3162003

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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.

US3162003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 24 AUG 2020

What was the treatment time? (00:00-23:59) 14:13 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 14:13

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

US3162003

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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

Collection date (dd MMM yyyy)	24 AUG 2020
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Collection time (00:00-23:59)	13:20 (24 HR)
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Collection date and time (derived)	24 AUG 2020 13:20
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US3162003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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	13:25	24 AUG 2020 13:25
Nasopharyngeal Swab 2	No		

US3162003

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

24 AUG 2020 14:49

PC Open Date & Time

24 AUG 2020 14:33

PC Close Date & Time

24 AUG 2020 17:03

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °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	24 AUG 2020 18:02
PC Open Date & Time	24 AUG 2020 17:58
PC Close Date & Time	25 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 12:46

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 12:28

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 16:58

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

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

28 AUG 2020 16:16

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 14:48

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 7

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

30 AUG 2020 12:02

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 8

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.

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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.

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 12:02

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 14:45

PC Open Date & Time

24 AUG 2020 14:33

PC Close Date & Time

24 AUG 2020 17:03

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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 18:03

PC Open Date & Time

24 AUG 2020 17:58

PC Close Date & Time

25 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

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 12:47

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

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

26 AUG 2020 12:28

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

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 16:58

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

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 16:16

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 14:48

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 12:03

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 14:46
PC Open Date & Time	24 AUG 2020 14:33
PC Close Date & Time	24 AUG 2020 17:03

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 18:03
PC Open Date & Time	24 AUG 2020 17:58
PC Close Date & Time	25 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 12:48
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 12:29
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 17:00
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

		Yes <input type="checkbox"/>
PC Time stamp	28 AUG 2020 16:17	
PC Open Date & Time	28 AUG 2020 12:00	
PC Close Date & Time	29 AUG 2020 11:59	

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 14:49
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:03
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp 31 AUG 2020 12:02

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3162003

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 AUG 2020 12:02
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3162003

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162003

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 07 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3162003

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162003

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162003

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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>)	11:23 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:23
Temperature (<i>xxx.x</i>)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162003

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3162003

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

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)	11:50 (24 HR)
Collection date and time (derived)	21 SEP 2020 11:50

US3162003

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 64

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

No ☒

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 SEP 2020 07:59:30

Patient Cloud Open Date & Time

26 SEP 2020 00:01

Patient Cloud Close Date & Time

30 SEP 2020 23:59

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 OCT 2020 08:31:45

Patient Cloud Open Date & Time

03 OCT 2020 00:01

Patient Cloud Close Date & Time

07 OCT 2020 23:59

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 78

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

No ☒

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 12:31:08

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

24 OCT 2020 07:15:41

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 07:10:28

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 09:04:20

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☒

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 NOV 2020 12:02:13

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 117

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

No ☒

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

18 NOV 2020 19:03:58

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 13:30:42

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 07:05:57

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 18:35:19

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 08:38:42

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 152

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

No ☒

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 19:38:04

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 159

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

No ☒

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 06:04:17

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 166

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

No ☒

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

06 JAN 2021 12:02:42

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 173

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

No ☒

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

13 JAN 2021 12:24:39

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

20 JAN 2021 07:03:44

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 18:28:16

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 13:30:11
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

24 FEB 2021 13:56:56

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 06:33:25

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☒

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 MAR 2021 08:31:52

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 MAR 2021 09:49:34
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

24 MAR 2021 15:59:24

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

Date and time of submission

31 MAR 2021 12:24:20

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

07 APR 2021 07:05:19

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 06:16:23

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

Date and time of submission

21 APR 2021 08:07:02

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 19:06:24

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 <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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 <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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 <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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 <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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 <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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 <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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

Patient Cloud Open Date & Time	10 NOV 2021 00:01
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Patient Cloud Close Date & Time	14 NOV 2021 23:59
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US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 <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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 <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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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="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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

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13 MAR 2022 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

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20 MAR 2022 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

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27 MAR 2022 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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="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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 <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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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="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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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="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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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="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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 <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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 <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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 <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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 768

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

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

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

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

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

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

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 ☐

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:23:27

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 06:33:45

US3162003

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162003

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:10

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162003

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3162003

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162003

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162003

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3162003

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162003

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 16:53:08

Generated On: 09 Jun 2021 15:23:27

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

Visit date (dd MMM yyyy)	19 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 16:53:08

Generated On: 09 Jun 2021 15:23:27

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3162003

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 16:53:08

Generated On: 09 Jun 2021 15:23:27

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3162003

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 16:53:08

Generated On: 09 Jun 2021 15:23:27

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 19 FEB 2021

Collection time (00:00-23:59) 10:02 (24 HR)

Collection date and time (derived) 19 FEB 2021 10:02

US3162003

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 16:53:08

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162003

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 16:53:08

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 16:53:07

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162003

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3162003

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Date of Contact	21 SEP 2020
Time of Contact	12:36
Date and Time of Contact (derived)	21 SEP 2020 12:36
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input 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"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

Date	21 SEP 2020
------	-------------

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

O2 Saturation	90 %
---------------	------

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

Temperature	36.3 C
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

	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)

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US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Symptom Day

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

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

Date	22 SEP 2020
------	-------------

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

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

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

Temperature	36.4 C
-------------	--------

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

Cough	None	<input 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

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EAB) (1725)

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

	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"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input 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"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

Date	23 SEP 2020
------	-------------

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

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

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

Temperature	37.1 C
-------------	--------

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

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

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

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

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EAB) (1725)

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

	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"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input 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"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

Date	24 SEP 2020
------	-------------

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

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

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

Temperature	36.3 C
-------------	--------

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

Cough	None <input 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

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EAB) (1725)

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Symptom Day

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

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

Date	20 SEP 2020
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Symptom Day

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

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

Date	19 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Symptom Day

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

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

Date	18 SEP 2020
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Symptom Day

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

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

Date	17 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Symptom Day

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

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

Date	16 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

Date	15 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

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Form: Symptom Log (10)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Symptom Day

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

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

Date	14 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

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Form: Symptom Log (11)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Symptom Day

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

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

Date	13 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Symptom Day

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

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

Date	12 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

Date	11 SEP 2020
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

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US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

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

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Date of Visit	21 SEP 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 type="radio"/> No <input checked="" type="radio"/>
Date of Test	21 SEP 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)	0

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3162003

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	23 SEP 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3162003

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

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	SICKD1

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	11:23 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:23
Height (xxx.x)	157.5 cm
Weight (xxx.x)	73.6 kg
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162003

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3162003

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 21:04:09

Generated On: 09 Jun 2021 15:23:27

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

21 SEP 2020

US3162003

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

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 16:53:07

Generated On: 09 Jun 2021 15:23:27

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

Visit date (dd MMM yyyy)	22 JAN 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
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US3162003

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 16:53:07

Generated On: 09 Jun 2021 15:23:27

Date of updated informed consent (dd MMM yyyy) 22 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 22 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3162003

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 16:53:07

Generated On: 09 Jun 2021 15:23:27

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

Collection date (dd MMM yyyy)	22 JAN 2021
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Collection time (00:00-23:59)	09:27 (24 HR)
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Collection date and time (derived)	22 JAN 2021 09:27
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US3162003

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Apr 2021 16:53:07

Generated On: 09 Jun 2021 15:23:27

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

Collection date (dd MMM yyyy)	22 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	09:29
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Collection Date and Time (derived)	22 JAN 2021 09:29
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US3162003

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

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162003

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3162003

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3162003

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 21:04:07

Generated On: 09 Jun 2021 15:23:27

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 06:58:43

Generated On: 09 Jun 2021 15:23:27

AEID

Adverse event

ACUTE CHOLECYSTITIS

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)

27 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

27 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☒

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 06:58:43

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Mar 2021 06:58:43

Generated On: 09 Jun 2021 15:23:27

AEID	USA-US074-2020-MRNA-1273-P30 1000004
Adverse event	ACUTE MYOCARDIAL INFARCTION
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)	07 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	08 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	8 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	10 SEP 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Mar 2021 06:58:43

Generated On: 09 Jun 2021 15:23:27

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	True
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	SUBJECT HAD ONSET OF ANTERIOR CHEST PAIN ON 07SEP. WENT TO ER 08SEP EVENING, DIAGNOSED WITH MYOCARDIAL INFARCTION, ADMITTED.
Serious Adverse Event Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Mar 2021 06:58:43

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Mar 2021 06:58:43

Generated On: 09 Jun 2021 15:23:27

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Mar 2021 06:58:43

Generated On: 09 Jun 2021 15:23:27

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
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)	

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Mar 2021 06:58:43

Generated On: 09 Jun 2021 15:23:27

AEID

Adverse event

NAUSEA DUE TO ACUTE
MYOCARDIAL INFARCTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

8 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

8 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Mar 2021 06:58:43

Generated On: 09 Jun 2021 15:23:27

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 checked="" type="radio"/> Dose Delayed <input 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 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)	

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Mar 2021 06:58:43

Generated On: 09 Jun 2021 15:23:27

AEID

Adverse event

SHORTNESS OF BREATH
SECONDARY TO CARVEDILOL

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Mar 2021 06:58:43

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <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 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)	

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Mar 2021 06:58:43

Generated On: 09 Jun 2021 15:23:27

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Mar 2021 06:58:43

Generated On: 09 Jun 2021 15:23:27

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 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)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 29 Mar 2021 06:58:43

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

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Folder: Adverse Events

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 21:04:08

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 21:22:43

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Name of Medication TRELEGY ELLIPTA

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 21:22:43

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	08 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication CERVICAL DISC DISEASE

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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Generated On: 09 Jun 2021 15:23:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 JUL 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication GLUCOSAMINE/CHONDROITIN

Prophylaxis Yes ☒
No ☐

Indication CERVICAL DISC DISEASE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 21:22:43

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Name of Medication OMEGA 3

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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	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)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 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"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication VITAMIN E

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 21:22:43

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 21:22:43

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	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 2005	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication ALBUTEROL SULFATE FOR
NEBULIZER .083%

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
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"/>

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 3

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

If dose unit is Other, specify LITERS

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication ACUTE MYOCARDIAL
INFARCTION

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	07 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 3.125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 21 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication TICAGRELOR

Prophylaxis Yes ☒
No ☐

Indication CORONARY ARTERY DISEASE

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 SEP 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication MORPHINE SULFATE

Prophylaxis Yes ☐
No ☒

Indication ACUTE MYOCARDIAL
INFARCTION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)		8 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE MYOCARDIAL
INFARCTION

Dose per administration 4400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	8 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 SEP 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"/>

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication HEPARIN INFUSION (DRIP)
25,000 IU IN 250 ML D5W

Prophylaxis Yes ☐
No ☒

Indication ACUTE MYOCARDIAL
INFARCTION

Dose per administration 8.7

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

If dose unit is Other, specify ML/HOUR

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	8 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE MYOCARDIAL
INFARCTION

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input checked="" type="checkbox"/>
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	8 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE MYOCARDIAL
INFARCTION

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	8 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 SEP 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"/>

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication NAUSEA DUE TO ACUTE
MYOCARDIAL INFARCTION

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)	8 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 SEP 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"/>

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication ACUTE MYOCARDIAL
INFARCTION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	7 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 SEP 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"/>

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication INFLUENZA 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

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EAB) (1725)

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	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)		15 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)		15 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"/>

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication PLAVIX

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 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"/>

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

Name of Medication TRIAMTERENE/HYDROCHLORO
THIAZIDE

Prophylaxis Yes ☐
No ☒

Indication BILATERAL LOWER
EXTREMITY EDEMA

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 08 Apr 2021 21:22:43

Generated On: 09 Jun 2021 15:23:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	15 DEC 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"/>

US3162003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3162003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Feb 2021 21:04:08

Generated On: 09 Jun 2021 15:23:27

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
09 SEP 2020	BALLOON ANGIOPLASTY OF MID-RIGHT CORONARY ARTERY	Adverse Event	
9 SEP 2020	LEFT HEART CATHETERIZATION	Adverse Event	
9 SEP 2020	LEFT AND RIGHT CORONARY ANGIOGRAPHY	Adverse Event	

US3162003

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:23:27

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

US3162003

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:23:27

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 ☐

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

SAEID	USA-US074-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

SAEID	USA-US074-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	10/SEP/2020 20:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

SAEID	USA-US074-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	12/SEP/2020 16:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

SAEID	USA-US074-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	17/SEP/2020 08:39
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

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

SAEID	USA-US074-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	23/SEP/2020 12:31
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

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

SAEID	USA-US074-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	06/OCT/2020 16:13
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

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 12 Feb 2021 21:04:09

Generated On: 09 Jun 2021 15:23:27

SAEID	USA-US074-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	15/OCT/2020 12:57
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

US3162003 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

US3162003

Form: Participant Creation

Generated On: 09 Jun 2021 15:23:27

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 01:36:54
User entered 'US3162003'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 20:39:22

US3162003

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 00:10:59
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:22:06

US3162003

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 00:10:59
User entered '27 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 20:39:23

US3162003

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 00:10:59
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:22:06

US3162003

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'SCRN'	System	28 Jul 2020 06:22:06

US3162003

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:27

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1, Visit2 Day29 and Visit3 Day57: Year of Birth (1945) recorded on this form does not match with the Year of birth (1955) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 11:39:23
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1, Visit2 Day29 and Visit3 Day57: Year of Birth (1945) recorded on this form does not match with the Year of birth (1955) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' answered with 'DATE CORRECTED IN PPD LAB RECORD' (Site from DM).	Judith Kirstein (b) (4)	19 Oct 2020 19:55:18
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1, Visit2 Day29 and Visit3 Day57: Year of Birth (1945) recorded on this form does not match with the Year of birth (1955) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:40:03
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 23:03:49
DataPoint Un-verified.	RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 23:30:14
User entered (b) (6) 1945' reason for change: Data Entry Error	RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 23:30:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:10:52
User closed query 'Thank you for submitting a DCF for the year of birth correction. Per the source, please confirm the year of birth is 1945 and update EDC accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 00:09:53

US3162003

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:27

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Query 'Thank you for submitting a DCF for the year of birth correction. Per the source, please confirm the year of birth is 1945 and update EDC accordingly. Thank you.' answered with 'i am unable to update as the screen is locked' (Site from CRA).	Jourdan Manfred (b) (4)	03 Sep 2020 01:34:15
User opened query 'Thank you for submitting a DCF for the year of birth correction. Per the source, please confirm the year of birth is 1945 and update EDC accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 17:51:30
User entered (b) (6) 1955'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 20:39:24

US3162003

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:27

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	16 Sep 2020 23:30:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 19:48:05
User closed query 'Please correct the subject's age, per the source it is 75. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 19:47:58
Query 'Please correct the subject's age, per the source it is 75. Thank you.' answered with 'Corrected' (Site from CRA).	Judith Kirstein (b) (4)	16 Sep 2020 19:27:50
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	16 Sep 2020 19:27:41
DataPoint Un-verified.	Judith Kirstein (b) (4)	16 Sep 2020 19:27:41
User entered '75' reason for change: Data Entry Error	Judith Kirstein (b) (4)	16 Sep 2020 19:27:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:10:52
User opened query 'Please correct the subject's age, per the source it is 75. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 00:10:44
User entered '65'	Jared Bradshaw (b) (4)	28 Jul 2020 06:23:24

US3162003

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:27

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'YEARS'	System	28 Jul 2020 06:23:24

US3162003

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:27

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered '75'	System	16 Sep 2020 23:30:14
User entered '65'	System	28 Jul 2020 00:27:13

US3162003

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:27

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:10:52
User entered 'Female (F)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:23:24

US3162003

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:27

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:10:52
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:23:24

US3162003

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:27

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:10:52
User entered 'I'	Jared Bradshaw (b) (4)	28 Jul 2020 06:23:24

US3162003

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:27

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:10:52
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:23:24

US3162003

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:27

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:10:52
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:23:24

US3162003

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:27

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:10:52
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:23:24

US3162003

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:27

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:10:52
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:23:24

US3162003

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:10:52
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:23:24

US3162003

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:27

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:10:52
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:23:24

US3162003

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:27

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:10:52
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:23:24

US3162003

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:27

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:10:52
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:23:24

US3162003

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:27

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 00:11:15
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 00:27:13

US3162003

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'Jul 2020'	System	28 Jul 2020 00:27:13

US3162003

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered '2020'	System	28 Jul 2020 00:27:13

US3162003

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:27

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 00:11:15
User entered 'Amendment 1 (1)'	Jared Bradshaw (b) (4)	28 Jul 2020 00:27:13

US3162003

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 00:11:15
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 00:27:13

US3162003

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 00:11:15
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 00:27:13

US3162003

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:27

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 00:11:15
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 00:27:13

US3162003

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:27

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 00:11:15
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 00:27:13

US3162003

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:27

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 00:11:15
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 20:39:23

US3162003

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:27

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'I'	System	28 Jul 2020 00:27:18

US3162003

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:52:04
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 00:27:18

US3162003

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:23:27

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:52:10
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:23:56

US3162003

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4)	28 Jul 2020 20:42:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	28 Jul 2020 20:42:55
Data point term sent to Coder	System	28 Jul 2020 06:26:24
User entered 'Chronic obstructive pulmonary disorder'	Jared Bradshaw (b) (4)	28 Jul 2020 06:25:25

US3162003

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 20:22:56
User entered 'un UNK 2005' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 20:22:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 06:25:25
User entered '00 UNK 2005' (non-conformant).	Jared Bradshaw (b) (4)	28 Jul 2020 06:25:25

US3162003

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:25:25

US3162003

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:25:25

US3162003

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:25:25

US3162003

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:25:25

US3162003

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'Jan 2005'	System	08 Aug 2020 20:22:56
User entered empty.	System	28 Jul 2020 06:25:25

US3162003

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered '2005'	System	08 Aug 2020 20:22:56
User entered empty.	System	28 Jul 2020 06:25:25

US3162003

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered empty.	System	28 Jul 2020 06:25:25

US3162003

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered empty.	System	28 Jul 2020 06:25:25

US3162003

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4)	28 Jul 2020 22:38:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	28 Jul 2020 22:38:57
Data point term sent to Coder	System	28 Jul 2020 06:26:26
User entered 'Hyperlipidema'	Jared Bradshaw (b) (4)	28 Jul 2020 06:25:57

US3162003

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 20:23:06
User entered 'un UNK 2005' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 20:23:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 06:25:57
User entered '00 UNK 2005' (non-conformant).	Jared Bradshaw (b) (4)	28 Jul 2020 06:25:57

US3162003

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:25:57

US3162003

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:25:57

US3162003

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:25:57

US3162003

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:25:57

US3162003

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'Jan 2005'	System	08 Aug 2020 20:23:06
User entered empty.	System	28 Jul 2020 06:25:57

US3162003

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered '2005'	System	08 Aug 2020 20:23:06
User entered empty.	System	28 Jul 2020 06:25:57

US3162003

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered empty.	System	28 Jul 2020 06:25:57

US3162003

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered empty.	System	28 Jul 2020 06:25:57

US3162003

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Wrist fracture, LLT: Wrist fracture - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 06:28:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 06:28:06
Data point term sent to Coder	System	28 Jul 2020 06:27:27
User entered 'Left wrist fracture'	Jared Bradshaw (b) (4)	28 Jul 2020 06:26:29

US3162003

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 20:23:18
User entered 'un Oct 2011' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 20:23:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 06:26:29
User entered '00 Oct 2011' (non-conformant).	Jared Bradshaw (b) (4)	28 Jul 2020 06:26:29

US3162003

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:26:29

US3162003

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:26:29

US3162003

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 23:05:04
User entered 'UN Mar 2012' reason for change: DataJourdan Manfred Entry Error	(b) (4)	11 Aug 2020 23:05:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 06:26:29
User entered '00 Mar 2012' (non-conformant).	Jared Bradshaw (b) (4)	28 Jul 2020 06:26:29

US3162003

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:26:29

US3162003

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'Oct 2011'	System	08 Aug 2020 20:23:18
User entered empty.	System	28 Jul 2020 06:26:29

US3162003

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered '2011'	System	08 Aug 2020 20:23:18
User entered empty.	System	28 Jul 2020 06:26:29

US3162003

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'Mar 2012'	System	11 Aug 2020 23:05:04
User entered empty.	System	28 Jul 2020 06:26:29

US3162003

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered '2012'	System	11 Aug 2020 23:05:04
User entered empty.	System	28 Jul 2020 06:26:29

US3162003

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc disorder, LLT: Cervical disc disease - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 06:28:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 06:28:07
Data point term sent to Coder	System	28 Jul 2020 06:27:26
User entered 'cervical disc disease'	Jared Bradshaw (b) (4)	28 Jul 2020 06:26:48

US3162003

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 20:23:27
User entered 'un Dec 2008' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 20:23:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 06:26:48
User entered '00 Dec 2008' (non-conformant).	Jared Bradshaw (b) (4)	28 Jul 2020 06:26:48

US3162003

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:26:48

US3162003

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:26:48

US3162003

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:26:48

US3162003

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:26:48

US3162003

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'Dec 2008'	System	08 Aug 2020 20:23:27
User entered empty.	System	28 Jul 2020 06:26:48

US3162003

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered '2008'	System	08 Aug 2020 20:23:27
User entered empty.	System	28 Jul 2020 06:26:48

US3162003

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered empty.	System	28 Jul 2020 06:26:48

US3162003

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered empty.	System	28 Jul 2020 06:26:48

US3162003

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:23:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:30:15
DataPoint Un-verified.	(b) (4), (b) (6)	02 Sep 2020 20:28:19
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopausal - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 06:31:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 06:31:13
Data point term sent to Coder	System	28 Jul 2020 06:30:28
User entered 'menopausal'	Jared Bradshaw (b) (4) (b) (4)	28 Jul 2020 06:30:24

US3162003

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:30:15
DataPoint Un-verified.	(b) (4), (b) (6)	02 Sep 2020 20:28:19
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 20:23:36
User entered 'un Jul 1988' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 20:23:36
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 06:30:24
User entered '00 Jul 1988' (non-conformant).	Jared Bradshaw (b) (4)	28 Jul 2020 06:30:24

US3162003

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:30:15
DataPoint Un-verified.	(b) (4), (b) (6)	02 Sep 2020 20:28:19
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:30:24

US3162003

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:23:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:30:15
DataPoint Un-verified.	(b) (4), (b) (6)	02 Sep 2020 20:28:19
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:30:24

US3162003

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:30:15
DataPoint Un-verified.	(b) (4), (b) (6)	02 Sep 2020 20:28:19
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:30:24

US3162003

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:23:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:30:15
DataPoint Un-verified.	(b) (4), (b) (6)	02 Sep 2020 20:28:19
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:53:13
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:30:24

US3162003

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'Jul 1988'	System	08 Aug 2020 20:23:36
User entered empty.	System	28 Jul 2020 06:30:24

US3162003

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered '1988'	System	08 Aug 2020 20:23:36
User entered empty.	System	28 Jul 2020 06:30:24

US3162003

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered empty.	System	28 Jul 2020 06:30:24

US3162003

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered empty.	System	28 Jul 2020 06:30:24

US3162003

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:23:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 07:00:38
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Ex-tobacco user, LLT: Ex-smoker - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 08:13:12
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 08:13:12
Data point term sent to Coder	System	05 Oct 2020 19:50:19
User entered 'PREVIOUS SMOKER'	Judith Kirstein (b) (4)	05 Oct 2020 19:50:02

US3162003

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 07:00:40
User entered 'UN UNK 1961'	Judith Kirstein (b) (4)	05 Oct 2020 19:50:02

US3162003

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 07:00:41
User entered '0'	Judith Kirstein (b) (4)	05 Oct 2020 19:50:02

US3162003

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:23:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 07:00:44
User entered 'No (N)'	Judith Kirstein (b) (4)	05 Oct 2020 19:50:02

US3162003

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 07:00:45
User entered 'UN UNK 2019'	Judith Kirstein (b) (4)	05 Oct 2020 19:50:02

US3162003

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:23:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 07:00:47
User entered '0'	Judith Kirstein (b) (4)	05 Oct 2020 19:50:02

US3162003

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'Jan 1961'	System	05 Oct 2020 19:50:02

US3162003

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered '1961'	System	05 Oct 2020 19:50:02

US3162003

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'Jan 2019'	System	05 Oct 2020 19:50:02

US3162003

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered '2019'	System	05 Oct 2020 19:50:02

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:55:57
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:12

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:55:58
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:12

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:00
User entered '13:12'	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:12

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered '27 Jul 2020 13:12'	System	28 Jul 2020 06:32:12

US3162003

Folder: Screening

Form: Vital Signs

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:02
User entered '62' in	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:12
DataPoint set to visible.	(b) (4) System	28 Jul 2020 00:27:18

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:05
User entered '164' lb	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:12
DataPoint set to visible.	(b) (4) System	28 Jul 2020 00:27:18

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
Amendment Manager: User entered '30.05871'	System	16 Sep 2020 23:37:01
User entered '30.1'	System	28 Jul 2020 06:32:12
DataPoint set to visible.	System	28 Jul 2020 00:27:18

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'kg/m2'	System	28 Jul 2020 06:32:12
DataPoint set to visible.	System	28 Jul 2020 00:27:18

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:11:16
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 02:45:48
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 00:25:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 00:25:48
DataPoint Un-verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:22
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:09
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 16:49:49
User entered '98.1' F	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:12

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:05:46
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 17:25:03
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 16:52:52
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	24 Sep 2020 16:52:47
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4)	24 Sep 2020 16:52:47
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 11:55:32
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:11:16
DataPoint Un-verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:26
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:09
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:12

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:11:16
DataPoint Un-verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:27
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:09
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:12

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:11:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4)	03 Sep 2020 00:25:48
DataPoint Un-verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:09
User entered '71'	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:12

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'bpm'	System	28 Jul 2020 06:32:12

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:11:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4)	03 Sep 2020 00:25:48
DataPoint Un-verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:31
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:09
User entered '19'	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:12

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'breaths/min'	System	28 Jul 2020 06:32:12

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:11:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4)	03 Sep 2020 00:25:48
DataPoint Un-verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:09
User entered '147'	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:12

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'mmHg'	System	28 Jul 2020 06:32:12

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:11:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4)	03 Sep 2020 00:25:48
DataPoint Un-verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:34
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:56:09
User entered '80'	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:12

US3162003

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'mmHg'	System	28 Jul 2020 06:32:12

US3162003

Folder: Screening

Form: Vital Signs

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[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33

US3162003

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:57:33
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:27

US3162003

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:57:33
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 12:28:36
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		24 Aug 2020 20:42:06
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:27

US3162003

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:23:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:57:48
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:58

US3162003

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:23:27

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:57:48
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:58

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:23:27

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:57:48
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:58

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:23:27

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:57:48
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:58

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:57:48
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:58

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:23:27

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:57:48
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:58

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Folder: Screening

Form: Childbearing Potential

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:57:48
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 23:04:19
User entered 'UN Jul 1988' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	11 Aug 2020 23:04:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 06:33:22
User closed query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	28 Jul 2020 06:33:22
User entered '00 Jul 1988' (non-conformant).	Jared Bradshaw (b) (4)	28 Jul 2020 06:33:22
User opened query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	28 Jul 2020 06:32:58
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:58

US3162003

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:23:27

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:57:48
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:32:58

US3162003

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:35:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 06:35:01
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	28 Jul 2020 06:35:01
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:34:17
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:35:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 06:35:01
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	28 Jul 2020 06:35:01
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:34:17
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:35:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 06:35:01
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	28 Jul 2020 06:35:01
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:34:17
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:35:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 06:35:01
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	28 Jul 2020 06:35:01
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:34:17
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

US3162003

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:35:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 06:35:01
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	28 Jul 2020 06:35:01
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:34:17
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:35:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 06:35:01
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	28 Jul 2020 06:35:01
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:34:17
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

US3162003

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:35:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 06:35:01
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	28 Jul 2020 06:35:01
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:34:17
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

US3162003

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:35:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 06:35:01
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	28 Jul 2020 06:35:01
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:34:17
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

US3162003

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:35:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 06:35:01
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	28 Jul 2020 06:35:01
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:34:17
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

US3162003

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:35:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 06:35:01
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	28 Jul 2020 06:35:01
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:34:17
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

US3162003

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:35:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 06:35:01
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	28 Jul 2020 06:35:01
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:34:17
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

US3162003

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User closed query 'If there is no "other", please leave it blank. Also, please remove the answer of "one" in the next question "Specify"' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 16:02:01
Query 'If there is no "other", please leave it blank. Also, please remove the answer of "one" in the next question "Specify" answered with 'Updated per query.' (Site from CRA).	Cynthia Kunakom (b) (4)	07 Sep 2020 20:16:02
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	07 Sep 2020 20:15:47
User opened query 'If there is no "other", please leave it blank. Also, please remove the answer of "one" in the next question "Specify"' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 17:59:33
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User entered empty; reason for change Per Query Resolution	Cynthia Kunakom (b) (4)	07 Sep 2020 20:15:47
User entered 'none' reason for change: New Information	Jared Bradshaw (b) (4)	28 Jul 2020 14:12:13
User entered 'Senior citizen'	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

US3162003

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

US3162003

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

US3162003

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

US3162003

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

US3162003

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

US3162003

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User entered 'I'	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

US3162003

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

US3162003

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:14
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:34:17

US3162003

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:27:47
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:41:00

US3162003

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:27:47
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 06:41:00

US3162003

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

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 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:27:47
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:41:00

US3162003

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'VISIT1'	System	28 Jul 2020 06:41:00

US3162003

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:12:59
User entered '27 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 20:44:05

US3162003

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:23:27

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:12:59
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:04:18
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:04:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Jul 2020 20:44:05
User entered '184039' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 20:44:05

US3162003

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:12:59
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 20:44:05

US3162003

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:23:27

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:12:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 05:09:54
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 04:18:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 04:18:52
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 04:18:52
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 06:42:54
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:42:54

US3162003

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:23:27

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:12:59
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:42:54

US3162003

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:12:59
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:42:54

US3162003

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:23:27

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:12:59
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:42:54

US3162003

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:23:27

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:12:59
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:42:54

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:45:40
User entered '62' in	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:45:40
User entered '74.4' kg	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:45:40
User entered '62' in	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:45:40
User entered '74.4' kg	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User accepted default value 'Pre-Dose (PREDOSE)'	Jared Bradshaw (b) (4) (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered '13:12'	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered '27 Jul 2020 13:12'	System	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered '98.1' F	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered '71'	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'bpm'	System	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered '19'	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'breaths/min'	System	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered '147'	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'mmHg'	System	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered '80'	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'mmHg'	System	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:45:40
User entered '62' in	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:45:40
User entered '74.4' kg	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User accepted default value 'Post-Dose (POSTDOSE)'	Jared Bradshaw (b) (4) (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
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)	13 Aug 2020 14:57:56
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'information is correct, vitals captured equal to or greater than 30 minutes post injection per protocol ' (Site from System).	Jourdan Manfred (b) (4)	11 Aug 2020 22:38:43
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		28 Jul 2020 06:50:38
User entered '14:55'	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered '27 Jul 2020 14:55'	System	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered '98.0' F	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered '77'	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'bpm'	System	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered '18'	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'breaths/min'	System	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered '151'	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'mmHg'	System	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:34
User entered '75'	Jared Bradshaw (b) (4)	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'mmHg'	System	28 Jul 2020 06:50:38

US3162003

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:27

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:47
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:45:20
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:53:09

US3162003

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:31:47
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:45:20
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 06:53:09

US3162003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:42
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 00:27:44

US3162003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:42
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 00:27:44

US3162003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:42
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 00:27:44

US3162003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'MRNA-1273 OR PLACEBO'	System	28 Jul 2020 00:27:44

US3162003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:42
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 00:27:44

US3162003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:42
User entered '14:19'	Jared Bradshaw (b) (4)	28 Jul 2020 00:27:44

US3162003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered '27 Jul 2020 14:19'	System	28 Jul 2020 00:27:44

US3162003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:42
User entered 'Left Arm (LEFT ARM)'	Jared Bradshaw (b) (4)	28 Jul 2020 00:27:44

US3162003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:42
User entered 'ONCE'	System	28 Jul 2020 00:27:44

US3162003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'INTRAMUSCULAR'	System	28 Jul 2020 00:27:44

US3162003

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:42:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:54:35

US3162003

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:42:26
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 06:54:35

US3162003

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:42:26
User entered '14:12'	Jared Bradshaw (b) (4)	28 Jul 2020 06:54:35

US3162003

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered '27 Jul 2020 14:12'	System	28 Jul 2020 06:54:35

US3162003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:23:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:42:59
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	28 Jul 2020 06:55:22
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	28 Jul 2020 06:55:22
User entered '27 Jul 2020' reason for change: New Information	Jared Bradshaw (b) (4)	28 Jul 2020 06:55:22
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	28 Jul 2020 06:55:04
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:55:04

US3162003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:23:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:55:04

US3162003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:23:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:42:59
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:55:04

US3162003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:23:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:42:59
User entered '14:16'	Jared Bradshaw (b) (4)	28 Jul 2020 06:55:04

US3162003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:23:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User entered '27 Jul 2020 14:16'	System	28 Jul 2020 06:55:22
User entered empty.	System	28 Jul 2020 06:55:04

US3162003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:23:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:55:04

US3162003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:23:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:42:59
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:55:04

US3162003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:23:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:42:59
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 06:55:04

US3162003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:23:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User entered empty.	System	28 Jul 2020 06:55:04

US3162003

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:43:11
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 06:55:28

US3162003

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User entered '1'	System	28 Jul 2020 06:55:28

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '27 Jul 2020 14:39'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '27 Jul 2020 17:09'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:06:53', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '80fde974-72d4-482f-9bb7-a968a95009fd'	System	28 Jul 2020 01:07:44
User entered 'Yes (Y)'	System	28 Jul 2020 01:07:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:07:16', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '80fde974-72d4-482f-9bb7-a968a95009fd'	System	28 Jul 2020 01:07:44
User entered '98.4'	System	28 Jul 2020 01:07:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:07:22', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '80fde974-72d4-482f-9bb7-a968a95009fd'	System	28 Jul 2020 01:07:44
User entered 'Yes (Y)'	System	28 Jul 2020 01:07:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took tramadol for cervical disc pain, which is in her medical history. Tramadol is a chronic med for her.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 17:02:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Judith Kirstein (b) (4)	12 Sep 2020 03:11:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:07:30', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '80fde974-72d4-482f-9bb7-a968a95009fd'	System	28 Jul 2020 01:07:44
User entered '1'	System	28 Jul 2020 01:07:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:07:30', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '80fde974-72d4-482f-9bb7-a968a95009fd'	System	28 Jul 2020 01:07:44
User entered '0'	System	28 Jul 2020 01:07:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:07:40', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '80fde974-72d4-482f-9bb7-a968a95009fd'	System	28 Jul 2020 01:07:44
User entered '27 Jul 2020 18:07'	System	28 Jul 2020 01:07:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '27 Jul 2020 18:04'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '28 Jul 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 2'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:01:59', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '5bae61e1-dbfa-4e9a-aef7-2fddfb195001'	System	28 Jul 2020 19:02:26
User entered 'Yes (Y)'	System	28 Jul 2020 19:02:26

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:02:06', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '5bae61e1-dbfa-4e9a-aef7-2fddfb195001'	System	28 Jul 2020 19:02:26
User entered '97.4'	System	28 Jul 2020 19:02:26

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:02:11', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '5bae61e1-dbfa-4e9a-aef7-2fddfb195001'	System	28 Jul 2020 19:02:26
User entered 'No (N)'	System	28 Jul 2020 19:02:26

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:02:23', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '5bae61e1-dbfa-4e9a-aef7-2fddfb195001'	System	28 Jul 2020 19:02:26
User entered '28 Jul 2020 12:02'	System	28 Jul 2020 19:02:26

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '28 Jul 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 3'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:03:17', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f39ca793-200d-485f-abff-985288d19cdc'	System	29 Jul 2020 19:04:01
User entered 'Yes (Y)'	System	29 Jul 2020 19:04:01

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:03:28', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f39ca793-200d-485f-abff-985288d19cdc'	System	29 Jul 2020 19:04:01
User entered '97.6'	System	29 Jul 2020 19:04:01

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:03:44', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f39ca793-200d-485f-abff-985288d19cdc'	System	29 Jul 2020 19:04:01
User entered 'No (N)'	System	29 Jul 2020 19:04:01

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:03:57', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f39ca793-200d-485f-abff-985288d19cdc'	System	29 Jul 2020 19:04:01
User entered '29 Jul 2020 12:03'	System	29 Jul 2020 19:04:01

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 4'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:02:28', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'c6597d67-f332-418c-b845-8c4037137c9d'	System	30 Jul 2020 19:02:53
User entered 'Yes (Y)'	System	30 Jul 2020 19:02:53

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:02:37', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'c6597d67-f332-418c-b845-8c4037137c9d'	System	30 Jul 2020 19:02:53
User entered '97.9'	System	30 Jul 2020 19:02:53

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:02:44', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'c6597d67-f332-418c-b845-8c4037137c9d'	System	30 Jul 2020 19:02:53
User entered 'No (N)'	System	30 Jul 2020 19:02:53

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:02:49', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'c6597d67-f332-418c-b845-8c4037137c9d'	System	30 Jul 2020 19:02:53
User entered '30 Jul 2020 12:02'	System	30 Jul 2020 19:02:53

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 5'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:37:05', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'fa864cf4-68a8-4a0a-8df9-c44b1a45771e'	System	01 Aug 2020 00:37:30
User entered 'Yes (Y)'	System	01 Aug 2020 00:37:30

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:37:18', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'fa864cf4-68a8-4a0a-8df9-c44b1a45771e'	System	01 Aug 2020 00:37:30
User entered '98.8'	System	01 Aug 2020 00:37:30

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:37:22', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'fa864cf4-68a8-4a0a-8df9-c44b1a45771e'	System	01 Aug 2020 00:37:30
User entered 'No (N)'	System	01 Aug 2020 00:37:30

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:37:27', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'fa864cf4-68a8-4a0a-8df9-c44b1a45771e'	System	01 Aug 2020 00:37:30
User entered '31 Jul 2020 17:37'	System	01 Aug 2020 00:37:30

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 6'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:38:11', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '742355bb-0c98-4613-af5c-85eec54aadd2'	System	02 Aug 2020 00:39:41
User entered 'Yes (Y)'	System	02 Aug 2020 00:39:41

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:38:49', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '742355bb-0c98-4613-af5c-85eec54aadd2'	System	02 Aug 2020 00:39:41
User entered '97.4'	System	02 Aug 2020 00:39:41

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:39:14', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '742355bb-0c98-4613-af5c-85eec54aadd2'	System	02 Aug 2020 00:39:41
User entered 'Yes (Y)'	System	02 Aug 2020 00:39:41

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took tramadol (a chronic med) for cervical disc pain (in med history)' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 17:03:23
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Judith Kirstein (b) (4)	12 Sep 2020 03:13:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:39:33', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '742355bb-0c98-4613-af5c-85eec54aadd2'	System	02 Aug 2020 00:39:41
User entered '1'	System	02 Aug 2020 00:39:41

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:39:33', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '742355bb-0c98-4613-af5c-85eec54aadd2'	System	02 Aug 2020 00:39:41
User entered '0'	System	02 Aug 2020 00:39:41

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:39:38', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '742355bb-0c98-4613-af5c-85eec54aadd2'	System	02 Aug 2020 00:39:41
User entered '01 Aug 2020 17:39'	System	02 Aug 2020 00:39:41

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 7'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:14:33', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '0c7da0d3-2c63-4736-8c94-d2d5a6c4ea91'	System	03 Aug 2020 00:15:25
User entered 'Yes (Y)'	System	03 Aug 2020 00:15:25

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:14:47', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '0c7da0d3-2c63-4736-8c94-d2d5a6c4ea91'	System	03 Aug 2020 00:15:25
User entered '97.7'	System	03 Aug 2020 00:15:25

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:15:11', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '0c7da0d3-2c63-4736-8c94-d2d5a6c4ea91'	System	03 Aug 2020 00:15:25
User entered 'No (N)'	System	03 Aug 2020 00:15:25

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:15:19', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '0c7da0d3-2c63-4736-8c94-d2d5a6c4ea91'	System	03 Aug 2020 00:15:25
User entered '02 Aug 2020 17:15'	System	03 Aug 2020 00:15:25

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '27 Jul 2020 14:39'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '27 Jul 2020 17:09'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:05:31', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b07a1153-df53-4b55-b46d-c148aa7e92e1'	System	28 Jul 2020 01:05:57
User entered 'None (1)'	System	28 Jul 2020 01:05:57

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:05:35', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b07a1153-df53-4b55-b46d-c148aa7e92e1'	System	28 Jul 2020 01:05:57
User entered 'No (N)'	System	28 Jul 2020 01:05:57

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:05:43', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b07a1153-df53-4b55-b46d-c148aa7e92e1'	System	28 Jul 2020 01:05:57
User entered 'No (N)'	System	28 Jul 2020 01:05:57

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:05:01', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b07a1153-df53-4b55-b46d-c148aa7e92e1'	System	28 Jul 2020 01:05:57
User entered 'None (1)'	System	28 Jul 2020 01:05:57

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:05:54', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b07a1153-df53-4b55-b46d-c148aa7e92e1'	System	28 Jul 2020 01:05:57
User entered '27 Jul 2020 18:05'	System	28 Jul 2020 01:05:57

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '27 Jul 2020 18:04'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '28 Jul 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 2'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:02:34', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'df3fc51a-741f-446c-a237-f1758aca10e3'	System	28 Jul 2020 19:03:29
User entered 'Does not interfere with activity (2)'	System	28 Jul 2020 19:03:29

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:02:38', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'df3fc51a-741f-446c-a237-f1758aca10e3'	System	28 Jul 2020 19:03:29
User entered 'No (N)'	System	28 Jul 2020 19:03:29

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:02:54', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'df3fc51a-741f-446c-a237-f1758aca10e3'	System	28 Jul 2020 19:03:29
User entered 'No (N)'	System	28 Jul 2020 19:03:29

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:03:03', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'df3fc51a-741f-446c-a237-f1758aca10e3'	System	28 Jul 2020 19:03:29
User entered 'None (1)'	System	28 Jul 2020 19:03:29

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:03:25', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'df3fc51a-741f-446c-a237-f1758aca10e3'	System	28 Jul 2020 19:03:29
User entered '28 Jul 2020 12:03'	System	28 Jul 2020 19:03:29

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '28 Jul 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 3'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:02:03', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '54def8b0-c206-4510-bb8d-7be69ba12014'	System	29 Jul 2020 19:02:57
User entered 'None (1)'	System	29 Jul 2020 19:02:57

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:02:07', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '54def8b0-c206-4510-bb8d-7be69ba12014'	System	29 Jul 2020 19:02:57
User entered 'No (N)'	System	29 Jul 2020 19:02:57

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:02:27', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '54def8b0-c206-4510-bb8d-7be69ba12014'	System	29 Jul 2020 19:02:57
User entered 'No (N)'	System	29 Jul 2020 19:02:57

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:02:48', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '54def8b0-c206-4510-bb8d-7be69ba12014'	System	29 Jul 2020 19:02:57
User entered 'None (1)'	System	29 Jul 2020 19:02:57

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:02:54', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '54def8b0-c206-4510-bb8d-7be69ba12014'	System	29 Jul 2020 19:02:57
User entered '29 Jul 2020 12:02'	System	29 Jul 2020 19:02:57

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 4'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:02:58', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e0b2cea8-0f5b-4ce7-8dc1-eb22c6cfbe2b'	System	30 Jul 2020 19:03:19
User entered 'None (1)'	System	30 Jul 2020 19:03:19

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:03:02', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e0b2cea8-0f5b-4ce7-8dc1-eb22c6cfbe2b'	System	30 Jul 2020 19:03:19
User entered 'No (N)'	System	30 Jul 2020 19:03:19

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:03:05', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e0b2cea8-0f5b-4ce7-8dc1-eb22c6cfbe2b'	System	30 Jul 2020 19:03:19
User entered 'No (N)'	System	30 Jul 2020 19:03:19

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:03:10', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e0b2cea8-0f5b-4ce7-8dc1-eb22c6cfbe2b'	System	30 Jul 2020 19:03:19
User entered 'None (1)'	System	30 Jul 2020 19:03:19

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:03:14', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e0b2cea8-0f5b-4ce7-8dc1-eb22c6cfbe2b'	System	30 Jul 2020 19:03:19
User entered '30 Jul 2020 12:03'	System	30 Jul 2020 19:03:19

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 5'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:37:35', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '39105ff6-36b5-4298-9226-922433ab6f68'	System	01 Aug 2020 00:38:05
User entered 'None (1)'	System	01 Aug 2020 00:38:05

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:37:39', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '39105ff6-36b5-4298-9226-922433ab6f68'	System	01 Aug 2020 00:38:05
User entered 'No (N)'	System	01 Aug 2020 00:38:05

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:37:42', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '39105ff6-36b5-4298-9226-922433ab6f68'	System	01 Aug 2020 00:38:05
User entered 'No (N)'	System	01 Aug 2020 00:38:05

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:37:47', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '39105ff6-36b5-4298-9226-922433ab6f68'	System	01 Aug 2020 00:38:05
User entered 'None (1)'	System	01 Aug 2020 00:38:05

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:38:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '39105ff6-36b5-4298-9226-922433ab6f68'	System	01 Aug 2020 00:38:05
User entered '31 Jul 2020 17:38'	System	01 Aug 2020 00:38:05

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 6'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:39:44', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'aea66f13-eed3-47ce-aaec-15d9b1c10b53'	System	02 Aug 2020 00:40:29
User entered 'None (1)'	System	02 Aug 2020 00:40:29

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:39:55', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'aea66f13-eed3-47ce-aaec-15d9b1c10b53'	System	02 Aug 2020 00:40:29
User entered 'No (N)'	System	02 Aug 2020 00:40:29

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:39:59', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'aea66f13-eed3-47ce-aaec-15d9b1c10b53'	System	02 Aug 2020 00:40:29
User entered 'No (N)'	System	02 Aug 2020 00:40:29

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:40:03', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'aea66f13-eed3-47ce-aaec-15d9b1c10b53'	System	02 Aug 2020 00:40:29
User entered 'None (1)'	System	02 Aug 2020 00:40:29

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:40:26', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'aea66f13-eed3-47ce-aaec-15d9b1c10b53'	System	02 Aug 2020 00:40:29
User entered '01 Aug 2020 17:40'	System	02 Aug 2020 00:40:29

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 7'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:15:37', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f6b44b6f-38ee-4aeb-a944-947075bce60e'	System	03 Aug 2020 00:16:09
User entered 'None (1)'	System	03 Aug 2020 00:16:09

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:15:46', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f6b44b6f-38ee-4aeb-a944-947075bce60e'	System	03 Aug 2020 00:16:09
User entered 'No (N)'	System	03 Aug 2020 00:16:09

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:15:51', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f6b44b6f-38ee-4aeb-a944-947075bce60e'	System	03 Aug 2020 00:16:09
User entered 'No (N)'	System	03 Aug 2020 00:16:09

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:16:02', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f6b44b6f-38ee-4aeb-a944-947075bce60e'	System	03 Aug 2020 00:16:09
User entered 'None (1)'	System	03 Aug 2020 00:16:09

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:16:06', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f6b44b6f-38ee-4aeb-a944-947075bce60e'	System	03 Aug 2020 00:16:09
User entered '02 Aug 2020 17:16'	System	03 Aug 2020 00:16:09

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '27 Jul 2020 14:39'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '27 Jul 2020 17:09'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:07:51', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '5dfb8af9-6e8b-4eef-8736-13dc8cc4816f'	System	28 Jul 2020 01:08:38
User entered 'None (0)'	System	28 Jul 2020 01:08:38

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:07:54', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '5dfb8af9-6e8b-4eef-8736-13dc8cc4816f'	System	28 Jul 2020 01:08:38
User entered 'None (0)'	System	28 Jul 2020 01:08:38

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:08:01', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '5dfb8af9-6e8b-4eef-8736-13dc8cc4816f'	System	28 Jul 2020 01:08:38
User entered 'None (0)'	System	28 Jul 2020 01:08:38

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:08:07', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '5dfb8af9-6e8b-4eef-8736-13dc8cc4816f'	System	28 Jul 2020 01:08:38
User entered 'None (0)'	System	28 Jul 2020 01:08:38

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:08:11', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '5dfb8af9-6e8b-4eef-8736-13dc8cc4816f'	System	28 Jul 2020 01:08:38
User entered 'None (0)'	System	28 Jul 2020 01:08:38

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:08:17', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '5dfb8af9-6e8b-4eef-8736-13dc8cc4816f'	System	28 Jul 2020 01:08:38
User entered 'None (0)'	System	28 Jul 2020 01:08:38

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:08:27', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '5dfb8af9-6e8b-4eef-8736-13dc8cc4816f'	System	28 Jul 2020 01:08:38
User entered 'No (N)'	System	28 Jul 2020 01:08:38

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-27T18:08:35', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '5dfb8af9-6e8b-4eef-8736-13dc8cc4816f'	System	28 Jul 2020 01:08:38
User entered '27 Jul 2020 18:08'	System	28 Jul 2020 01:08:38

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '27 Jul 2020 18:04'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '28 Jul 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 2'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:03:31', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1685dcdd-82ab-43f1-ac23-a6137eb8aa14'	System	28 Jul 2020 19:04:37
User entered 'None (0)'	System	28 Jul 2020 19:04:37

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:03:56', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1685dcdd-82ab-43f1-ac23-a6137eb8aa14'	System	28 Jul 2020 19:04:37
User entered 'None (0)'	System	28 Jul 2020 19:04:37

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:04:04', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1685dcdd-82ab-43f1-ac23-a6137eb8aa14'	System	28 Jul 2020 19:04:37
User entered 'None (0)'	System	28 Jul 2020 19:04:37

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:04:09', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1685dcdd-82ab-43f1-ac23-a6137eb8aa14'	System	28 Jul 2020 19:04:37
User entered 'None (0)'	System	28 Jul 2020 19:04:37

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:04:13', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1685dcdd-82ab-43f1-ac23-a6137eb8aa14'	System	28 Jul 2020 19:04:37
User entered 'None (0)'	System	28 Jul 2020 19:04:37

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:04:16', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1685dcdd-82ab-43f1-ac23-a6137eb8aa14'	System	28 Jul 2020 19:04:37
User entered 'None (0)'	System	28 Jul 2020 19:04:37

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:04:22', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1685dcdd-82ab-43f1-ac23-a6137eb8aa14'	System	28 Jul 2020 19:04:37
User entered 'No (N)'	System	28 Jul 2020 19:04:37

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-28T12:04:33', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1685dcdd-82ab-43f1-ac23-a6137eb8aa14'	System	28 Jul 2020 19:04:37
User entered '28 Jul 2020 12:04'	System	28 Jul 2020 19:04:37

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '28 Jul 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 3'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:00:55', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '4df9d142-62ff-4334-998b-6723bd3923a2'	System	29 Jul 2020 19:01:52
User entered 'None (0)'	System	29 Jul 2020 19:01:52

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:01:09', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '4df9d142-62ff-4334-998b-6723bd3923a2'	System	29 Jul 2020 19:01:52
User entered 'None (0)'	System	29 Jul 2020 19:01:52

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:01:20', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '4df9d142-62ff-4334-998b-6723bd3923a2'	System	29 Jul 2020 19:01:52
User entered 'None (0)'	System	29 Jul 2020 19:01:52

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:01:24', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '4df9d142-62ff-4334-998b-6723bd3923a2'	System	29 Jul 2020 19:01:52
User entered 'None (0)'	System	29 Jul 2020 19:01:52

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:01:28', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '4df9d142-62ff-4334-998b-6723bd3923a2'	System	29 Jul 2020 19:01:52
User entered 'None (0)'	System	29 Jul 2020 19:01:52

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:01:31', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '4df9d142-62ff-4334-998b-6723bd3923a2'	System	29 Jul 2020 19:01:52
User entered 'None (0)'	System	29 Jul 2020 19:01:52

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:01:35', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '4df9d142-62ff-4334-998b-6723bd3923a2'	System	29 Jul 2020 19:01:52
User entered 'No (N)'	System	29 Jul 2020 19:01:52

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-29T12:01:49', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '4df9d142-62ff-4334-998b-6723bd3923a2'	System	29 Jul 2020 19:01:52
User entered '29 Jul 2020 12:01'	System	29 Jul 2020 19:01:52

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 4'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:03:21', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bdba2bc7-ffc8-4977-b835-c480a0ef3956'	System	30 Jul 2020 19:03:53
User entered 'None (0)'	System	30 Jul 2020 19:03:53

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:03:24', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bdba2bc7-ffc8-4977-b835-c480a0ef3956'	System	30 Jul 2020 19:03:53
User entered 'None (0)'	System	30 Jul 2020 19:03:53

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:03:31', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bdba2bc7-ffc8-4977-b835-c480a0ef3956'	System	30 Jul 2020 19:03:53
User entered 'None (0)'	System	30 Jul 2020 19:03:53

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:03:36', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bdba2bc7-ffc8-4977-b835-c480a0ef3956'	System	30 Jul 2020 19:03:53
User entered 'None (0)'	System	30 Jul 2020 19:03:53

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:03:39', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bdba2bc7-ffc8-4977-b835-c480a0ef3956'	System	30 Jul 2020 19:03:53
User entered 'None (0)'	System	30 Jul 2020 19:03:53

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:03:42', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bdba2bc7-ffc8-4977-b835-c480a0ef3956'	System	30 Jul 2020 19:03:53
User entered 'None (0)'	System	30 Jul 2020 19:03:53

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:03:46', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bdba2bc7-ffc8-4977-b835-c480a0ef3956'	System	30 Jul 2020 19:03:53
User entered 'No (N)'	System	30 Jul 2020 19:03:53

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-30T12:03:50', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bdba2bc7-ffc8-4977-b835-c480a0ef3956'	System	30 Jul 2020 19:03:53
User entered '30 Jul 2020 12:03'	System	30 Jul 2020 19:03:53

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 5'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:39:06', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '11b4f5ce-e584-4f1a-a69c-c7aa8977082d'	System	01 Aug 2020 00:39:32
User entered 'None (0)'	System	01 Aug 2020 00:39:32

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:39:09', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '11b4f5ce-e584-4f1a-a69c-c7aa8977082d'	System	01 Aug 2020 00:39:32
User entered 'None (0)'	System	01 Aug 2020 00:39:32

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:39:13', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '11b4f5ce-e584-4f1a-a69c-c7aa8977082d'	System	01 Aug 2020 00:39:32
User entered 'None (0)'	System	01 Aug 2020 00:39:32

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:39:16', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '11b4f5ce-e584-4f1a-a69c-c7aa8977082d'	System	01 Aug 2020 00:39:32
User entered 'None (0)'	System	01 Aug 2020 00:39:32

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:39:19', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '11b4f5ce-e584-4f1a-a69c-c7aa8977082d'	System	01 Aug 2020 00:39:32
User entered 'None (0)'	System	01 Aug 2020 00:39:32

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:39:22', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '11b4f5ce-e584-4f1a-a69c-c7aa8977082d'	System	01 Aug 2020 00:39:32
User entered 'None (0)'	System	01 Aug 2020 00:39:32

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:39:26', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '11b4f5ce-e584-4f1a-a69c-c7aa8977082d'	System	01 Aug 2020 00:39:32
User entered 'No (N)'	System	01 Aug 2020 00:39:32

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-07-31T17:39:29', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '11b4f5ce-e584-4f1a-a69c-c7aa8977082d'	System	01 Aug 2020 00:39:32
User entered '31 Jul 2020 17:39'	System	01 Aug 2020 00:39:32

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 6'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:40:32', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '2c81890b-c5dd-4eb8-bea2-fb40ea0ec77d'	System	02 Aug 2020 00:41:03
User entered 'None (0)'	System	02 Aug 2020 00:41:03

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:40:34', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '2c81890b-c5dd-4eb8-bea2-fb40ea0ec77d'	System	02 Aug 2020 00:41:03
User entered 'None (0)'	System	02 Aug 2020 00:41:03

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:40:37', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '2c81890b-c5dd-4eb8-bea2-fb40ea0ec77d'	System	02 Aug 2020 00:41:03
User entered 'None (0)'	System	02 Aug 2020 00:41:03

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:40:40', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '2c81890b-c5dd-4eb8-bea2-fb40ea0ec77d'	System	02 Aug 2020 00:41:03
User entered 'None (0)'	System	02 Aug 2020 00:41:03

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:40:43', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '2c81890b-c5dd-4eb8-bea2-fb40ea0ec77d'	System	02 Aug 2020 00:41:03
User entered 'None (0)'	System	02 Aug 2020 00:41:03

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:40:47', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '2c81890b-c5dd-4eb8-bea2-fb40ea0ec77d'	System	02 Aug 2020 00:41:03
User entered 'None (0)'	System	02 Aug 2020 00:41:03

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:40:55', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '2c81890b-c5dd-4eb8-bea2-fb40ea0ec77d'	System	02 Aug 2020 00:41:03
User entered 'No (N)'	System	02 Aug 2020 00:41:03

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-01T17:40:59', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '2c81890b-c5dd-4eb8-bea2-fb40ea0ec77d'	System	02 Aug 2020 00:41:03
User entered '01 Aug 2020 17:40'	System	02 Aug 2020 00:41:03

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 7'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:16:19', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b4aadba3-de0a-4476-ab64-b4ca9e80abad'	System	03 Aug 2020 00:17:05
User entered 'None (0)'	System	03 Aug 2020 00:17:05

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:16:24', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b4aadba3-de0a-4476-ab64-b4ca9e80abad'	System	03 Aug 2020 00:17:05
User entered 'None (0)'	System	03 Aug 2020 00:17:05

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:16:28', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b4aadba3-de0a-4476-ab64-b4ca9e80abad'	System	03 Aug 2020 00:17:05
User entered 'None (0)'	System	03 Aug 2020 00:17:05

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:16:37', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b4aadba3-de0a-4476-ab64-b4ca9e80abad'	System	03 Aug 2020 00:17:05
User entered 'None (0)'	System	03 Aug 2020 00:17:05

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:16:41', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b4aadba3-de0a-4476-ab64-b4ca9e80abad'	System	03 Aug 2020 00:17:05
User entered 'None (0)'	System	03 Aug 2020 00:17:05

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:16:45', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b4aadba3-de0a-4476-ab64-b4ca9e80abad'	System	03 Aug 2020 00:17:05
User entered 'None (0)'	System	03 Aug 2020 00:17:05

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:16:50', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b4aadba3-de0a-4476-ab64-b4ca9e80abad'	System	03 Aug 2020 00:17:05
User entered 'No (N)'	System	03 Aug 2020 00:17:05

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66fd9f6b4e9059bc)', Time: '2020-08-02T17:16:59', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b4aadba3-de0a-4476-ab64-b4ca9e80abad'	System	03 Aug 2020 00:17:05
User entered '02 Aug 2020 17:16'	System	03 Aug 2020 00:17:05

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 00:27:44

US3162003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:59:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:41:32

US3162003

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:11:46
DataPoint Un-verified.	Jared Bradshaw (b) (4)	10 Nov 2020 17:14:39
User entered '03 Aug 2020' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	10 Nov 2020 17:14:39
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:59:38
User entered '3 Aug 2020'	Jared Bradshaw (b) (4)	05 Aug 2020 04:41:32

US3162003

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:59:38
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:41:32

US3162003

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:59:38
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:41:32

US3162003

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:59:43
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:41:36

US3162003

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User entered 'I'	System	05 Aug 2020 04:41:36

US3162003

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:00:06
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	12 Aug 2020 05:23:18

US3162003

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:00:06
User entered '10 Aug 2020'	Jared Bradshaw (b) (4)	12 Aug 2020 05:23:18

US3162003

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:00:06
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4)	12 Aug 2020 05:23:18

US3162003

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:00:06
User entered empty.	Jared Bradshaw (b) (4)	12 Aug 2020 05:23:18

US3162003

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:00:14
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	12 Aug 2020 05:23:11

US3162003

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User entered 'I'	System	12 Aug 2020 05:23:11

US3162003

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:00:29
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	18 Aug 2020 05:15:14

US3162003

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:00:29
User entered '17 Aug 2020'	Jared Bradshaw (b) (4)	18 Aug 2020 05:15:14

US3162003

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:00:29
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4)	18 Aug 2020 05:15:14

US3162003

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:00:29
User entered empty.	Jared Bradshaw (b) (4)	18 Aug 2020 05:15:14

US3162003

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:00:35
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	18 Aug 2020 05:15:18

US3162003

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User entered 'I'	System	18 Aug 2020 05:15:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:58:54
User entered 'Yes (Y)'	Jourdan Manfred (b) (4)	24 Aug 2020 20:42:06

US3162003

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:58:54
User entered '24 Aug 2020'	Jourdan Manfred (b) (4)	24 Aug 2020 20:42:06

US3162003

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

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 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:58:54
User entered 'Clinic (Clinic)'	Jourdan Manfred (b) (4)	24 Aug 2020 20:42:06

US3162003

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'VISIT2'	System	24 Aug 2020 20:42:06

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User accepted default value 'Pre-Dose (PREDOSE)'	Jourdan Manfred (b) (4) (b) (4)	24 Aug 2020 20:44:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered 'Yes (Y)'	Jourdan Manfred (b) (4)	24 Aug 2020 20:44:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered '24 Aug 2020'	Jourdan Manfred (b) (4)	24 Aug 2020 20:44:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered '12:59'	Jourdan Manfred (b) (4)	24 Aug 2020 20:44:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered '24 Aug 2020 12:59'	System	24 Aug 2020 20:44:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered '97.1' F	Jourdan Manfred (b) (4)	24 Aug 2020 20:44:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered 'Oral (Oral)'	Jourdan Manfred (b) (4)	24 Aug 2020 20:44:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered empty.	Jourdan Manfred (b) (4)	24 Aug 2020 20:44:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered '79'	Jourdan Manfred (b) (4)	24 Aug 2020 20:44:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'bpm'	System	24 Aug 2020 20:44:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered '16'	Jourdan Manfred (b) (4)	24 Aug 2020 20:44:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'breaths/min'	System	24 Aug 2020 20:44:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered '131'	Jourdan Manfred (b) (4)	24 Aug 2020 20:44:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'mmHg'	System	24 Aug 2020 20:44:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered '66'	Jourdan Manfred (b) (4)	24 Aug 2020 20:44:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'mmHg'	System	24 Aug 2020 20:44:18

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User accepted default value 'Post-Dose (POSTDOSE)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 15:08:05

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:08:05

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered '24 Aug 2020'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:08:05

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered '14:49'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:08:05

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered '24 Aug 2020 14:49'	System	28 Aug 2020 15:08:05

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered '97.6' F	Cynthia Kunakom (b) (4)	28 Aug 2020 15:08:05

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:08:05

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:08:05

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered '74'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:08:05

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'bpm'	System	28 Aug 2020 15:08:05

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered '16'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:08:05

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'breaths/min'	System	28 Aug 2020 15:08:05

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered '128'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:08:05

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'mmHg'	System	28 Aug 2020 15:08:05

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:09:38
User entered '73'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:08:05

US3162003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'mmHg'	System	28 Aug 2020 15:08:05

US3162003

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:27

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:06:48
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:06:56

US3162003

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:06:48
User entered '24 Aug 2020'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:06:56

US3162003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:06:20
User entered 'Yes (Y)'	Jourdan Manfred (b) (4)	24 Aug 2020 21:13:52

US3162003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:06:20
User entered empty.	Jourdan Manfred (b) (4)	24 Aug 2020 21:13:52

US3162003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:06:20
User entered empty.	Jourdan Manfred (b) (4)	24 Aug 2020 21:13:52

US3162003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 21:13:52

US3162003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:06:20
User entered '24 Aug 2020'	Jourdan Manfred (b) (4)	24 Aug 2020 21:13:52

US3162003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:06:20
User entered '14:13'	Jourdan Manfred (b) (4)	24 Aug 2020 21:13:52

US3162003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered '24 Aug 2020 14:13'	System	24 Aug 2020 21:13:52

US3162003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:06:20
User entered 'Left Arm (LEFT ARM)'	Jourdan Manfred (b) (4)	24 Aug 2020 21:13:52

US3162003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:06:20
User entered 'ONCE'	System	24 Aug 2020 21:13:52

US3162003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:27

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 21:13:52

US3162003

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:07:20
User entered 'Yes (Y)'	Jourdan Manfred (b) (4)	24 Aug 2020 20:44:54

US3162003

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:07:20
User entered '24 Aug 2020'	Jourdan Manfred (b) (4)	24 Aug 2020 20:44:54

US3162003

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:07:20
User entered '13:20'	Jourdan Manfred (b) (4)	24 Aug 2020 20:44:54

US3162003

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered '24 Aug 2020 13:20'	System	24 Aug 2020 20:44:54

US3162003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:23:27

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:11:54
User entered '24 Aug 2020'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:07:15

US3162003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:23:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:07:15

US3162003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:23:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:11:54
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:07:15

US3162003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:23:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:11:54
User entered '13:25'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:07:15

US3162003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:23:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered '24 Aug 2020 13:25'	System	28 Aug 2020 15:07:15

US3162003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:23:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:07:15

US3162003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:23:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:11:54
User entered 'No (N)'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:07:15

US3162003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:23:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:11:54
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:07:15

US3162003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:23:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered empty.	System	28 Aug 2020 15:07:15

US3162003

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 20:12:01
User entered 'Yes (Y)'	Jourdan Manfred (b) (4)	24 Aug 2020 20:45:04

US3162003

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered '1'	System	24 Aug 2020 20:45:04

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:49:03', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '80e2cbaf-d619-4951-81a0-8505795f0988'	System	24 Aug 2020 21:49:32
User entered 'Yes (Y)'	System	24 Aug 2020 21:49:32

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:49:13', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '80e2cbaf-d619-4951-81a0-8505795f0988'	System	24 Aug 2020 21:49:32
User entered '97.6'	System	24 Aug 2020 21:49:32

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:49:20', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '80e2cbaf-d619-4951-81a0-8505795f0988'	System	24 Aug 2020 21:49:32
User entered 'No (N)'	System	24 Aug 2020 21:49:32

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:49:27', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '80e2cbaf-d619-4951-81a0-8505795f0988'	System	24 Aug 2020 21:49:32
User entered '24 Aug 2020 14:49'	System	24 Aug 2020 21:49:32

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '24 Aug 2020 14:33'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '24 Aug 2020 17:03'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:02:03', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'abb2447e-68a5-4808-bfe0-03bee8edbb7a'	System	25 Aug 2020 01:02:32
User entered 'Yes (Y)'	System	25 Aug 2020 01:02:32

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:02:11', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'abb2447e-68a5-4808-bfe0-03bee8edbb7a'	System	25 Aug 2020 01:02:32
User entered '97.6'	System	25 Aug 2020 01:02:32

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:02:17', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'abb2447e-68a5-4808-bfe0-03bee8edbb7a'	System	25 Aug 2020 01:02:32
User entered 'No (N)'	System	25 Aug 2020 01:02:32

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:02:25', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'abb2447e-68a5-4808-bfe0-03bee8edbb7a'	System	25 Aug 2020 01:02:32
User entered '24 Aug 2020 18:02'	System	25 Aug 2020 01:02:32

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '24 Aug 2020 17:58'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 2'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:46:08', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '0ef11d26-baff-4d52-a552-a443102e914d'	System	25 Aug 2020 19:46:51
User entered 'Yes (Y)'	System	25 Aug 2020 19:46:51

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:46:29', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '0ef11d26-baff-4d52-a552-a443102e914d'	System	25 Aug 2020 19:46:51
User entered '97.7'	System	25 Aug 2020 19:46:51

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:46:34', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '0ef11d26-baff-4d52-a552-a443102e914d'	System	25 Aug 2020 19:46:51
User entered 'No (N)'	System	25 Aug 2020 19:46:51

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:46:42', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '0ef11d26-baff-4d52-a552-a443102e914d'	System	25 Aug 2020 19:46:51
User entered '25 Aug 2020 12:46'	System	25 Aug 2020 19:46:51

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 3'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:28:24', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'c0628eea-0154-4350-adfe-e383214d659d'	System	26 Aug 2020 19:28:47
User entered 'Yes (Y)'	System	26 Aug 2020 19:28:47

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:28:31', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'c0628eea-0154-4350-adfe-e383214d659d'	System	26 Aug 2020 19:28:47
User entered '96.8'	System	26 Aug 2020 19:28:47

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:28:35', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'c0628eea-0154-4350-adfe-e383214d659d'	System	26 Aug 2020 19:28:47
User entered 'No (N)'	System	26 Aug 2020 19:28:47

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:28:40', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'c0628eea-0154-4350-adfe-e383214d659d'	System	26 Aug 2020 19:28:47
User entered '26 Aug 2020 12:28'	System	26 Aug 2020 19:28:47

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 4'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T16:57:39', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '61c845a2-43e8-40ae-941a-0a2f2eb9da4e'	System	27 Aug 2020 23:58:30
User entered 'Yes (Y)'	System	27 Aug 2020 23:58:30

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T16:57:59', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '61c845a2-43e8-40ae-941a-0a2f2eb9da4e'	System	27 Aug 2020 23:58:30
User entered '97.9'	System	27 Aug 2020 23:58:30

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T16:58:03', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '61c845a2-43e8-40ae-941a-0a2f2eb9da4e'	System	27 Aug 2020 23:58:30
User entered 'No (N)'	System	27 Aug 2020 23:58:30

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T16:58:24', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '61c845a2-43e8-40ae-941a-0a2f2eb9da4e'	System	27 Aug 2020 23:58:30
User entered '27 Aug 2020 16:58'	System	27 Aug 2020 23:58:30

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 5'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:15:41', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '7609f42f-a924-45d4-be81-728582d3843a'	System	28 Aug 2020 23:16:34
User entered 'Yes (Y)'	System	28 Aug 2020 23:16:34

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:15:54', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '7609f42f-a924-45d4-be81-728582d3843a'	System	28 Aug 2020 23:16:34
User entered '98.7'	System	28 Aug 2020 23:16:34

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:16:14', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '7609f42f-a924-45d4-be81-728582d3843a'	System	28 Aug 2020 23:16:34
User entered 'No (N)'	System	28 Aug 2020 23:16:34

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:16:28', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '7609f42f-a924-45d4-be81-728582d3843a'	System	28 Aug 2020 23:16:34
User entered '28 Aug 2020 16:16'	System	28 Aug 2020 23:16:34

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 6'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:47:48', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1ebc3c95-49b8-49c7-8530-251d0edd70f6'	System	29 Aug 2020 21:48:21
User entered 'Yes (Y)'	System	29 Aug 2020 21:48:21

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:47:57', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1ebc3c95-49b8-49c7-8530-251d0edd70f6'	System	29 Aug 2020 21:48:21
User entered '97.6'	System	29 Aug 2020 21:48:21

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:48:08', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1ebc3c95-49b8-49c7-8530-251d0edd70f6'	System	29 Aug 2020 21:48:21
User entered 'No (N)'	System	29 Aug 2020 21:48:21

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:48:16', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1ebc3c95-49b8-49c7-8530-251d0edd70f6'	System	29 Aug 2020 21:48:21
User entered '29 Aug 2020 14:48'	System	29 Aug 2020 21:48:21

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 7'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:01:52', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e53dd24a-0752-4683-a7a9-41fc485d3d73'	System	30 Aug 2020 19:03:06
User entered 'Yes (Y)'	System	30 Aug 2020 19:03:06

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:01:58', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e53dd24a-0752-4683-a7a9-41fc485d3d73'	System	30 Aug 2020 19:03:06
User entered '97.0'	System	30 Aug 2020 19:03:06

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:02:37', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e53dd24a-0752-4683-a7a9-41fc485d3d73'	System	30 Aug 2020 19:03:06
User entered 'Yes (Y)'	System	30 Aug 2020 19:03:06

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Tramadol (chronic med) taken for cervical disc pain (chronic problem)' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 17:01:57
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:02:48', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e53dd24a-0752-4683-a7a9-41fc485d3d73'	Judith Kirstein (b) (4)	12 Sep 2020 03:18:13
User entered '1'	System	30 Aug 2020 19:03:06
	System	30 Aug 2020 19:03:06
	System	30 Aug 2020 19:03:06

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:02:48', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e53dd24a-0752-4683-a7a9-41fc485d3d73'	System	30 Aug 2020 19:03:06
User entered '0'	System	30 Aug 2020 19:03:06

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:02:57', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e53dd24a-0752-4683-a7a9-41fc485d3d73'	System	30 Aug 2020 19:03:06
User entered '30 Aug 2020 12:02'	System	30 Aug 2020 19:03:06

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	30 Aug 2020 19:03:06
User entered 'Day 8'	System	30 Aug 2020 19:03:06

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:23:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-31T12:01:54', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b73e9d64-6acf-49fe-9c8a-9cba0d4d8271'	System	31 Aug 2020 19:05:14
User entered 'Yes (Y)'	System	31 Aug 2020 19:05:14

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:23:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-31T12:02:05', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b73e9d64-6acf-49fe-9c8a-9cba0d4d8271'	System	31 Aug 2020 19:05:14
User entered '97.7'	System	31 Aug 2020 19:05:14

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:23:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-31T12:02:09', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b73e9d64-6acf-49fe-9c8a-9cba0d4d8271'	System	31 Aug 2020 19:05:14
User entered 'No (N)'	System	31 Aug 2020 19:05:14

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-31T12:02:13', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b73e9d64-6acf-49fe-9c8a-9cba0d4d8271'	System	31 Aug 2020 19:05:14
User entered '31 Aug 2020 12:02'	System	31 Aug 2020 19:05:14

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 19:03:06

US3162003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 19:03:06

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:45:04', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '7f421a68-55a4-4bdf-af16-29e82374a19b'	System	24 Aug 2020 21:45:51
User entered 'None (1)'	System	24 Aug 2020 21:45:51

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:45:17', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '7f421a68-55a4-4bdf-af16-29e82374a19b'	System	24 Aug 2020 21:45:51
User entered 'No (N)'	System	24 Aug 2020 21:45:51

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:45:29', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '7f421a68-55a4-4bdf-af16-29e82374a19b'	System	24 Aug 2020 21:45:51
User entered 'No (N)'	System	24 Aug 2020 21:45:51

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:45:35', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '7f421a68-55a4-4bdf-af16-29e82374a19b'	System	24 Aug 2020 21:45:51
User entered 'None (1)'	System	24 Aug 2020 21:45:51

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:45:46', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '7f421a68-55a4-4bdf-af16-29e82374a19b'	System	24 Aug 2020 21:45:51
User entered '24 Aug 2020 14:45'	System	24 Aug 2020 21:45:51

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '24 Aug 2020 14:33'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '24 Aug 2020 17:03'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:02:37', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '988f7443-f442-4f45-be34-c51d8581e245'	System	25 Aug 2020 01:03:08
User entered 'None (1)'	System	25 Aug 2020 01:03:08

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:02:40', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '988f7443-f442-4f45-be34-c51d8581e245'	System	25 Aug 2020 01:03:08
User entered 'No (N)'	System	25 Aug 2020 01:03:08

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:02:47', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '988f7443-f442-4f45-be34-c51d8581e245'	System	25 Aug 2020 01:03:08
User entered 'No (N)'	System	25 Aug 2020 01:03:08

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:02:55', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '988f7443-f442-4f45-be34-c51d8581e245'	System	25 Aug 2020 01:03:08
User entered 'None (1)'	System	25 Aug 2020 01:03:08

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:03:02', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '988f7443-f442-4f45-be34-c51d8581e245'	System	25 Aug 2020 01:03:08
User entered '24 Aug 2020 18:03'	System	25 Aug 2020 01:03:08

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '24 Aug 2020 17:58'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 2'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:46:55', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '192c695b-4bfa-419b-8a7e-efbb0b7283ad'	System	25 Aug 2020 19:47:41
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 19:47:41

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:46:59', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '192c695b-4bfa-419b-8a7e-efbb0b7283ad'	System	25 Aug 2020 19:47:41
User entered 'No (N)'	System	25 Aug 2020 19:47:41

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:47:03', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '192c695b-4bfa-419b-8a7e-efbb0b7283ad'	System	25 Aug 2020 19:47:41
User entered 'No (N)'	System	25 Aug 2020 19:47:41

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:47:16', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '192c695b-4bfa-419b-8a7e-efbb0b7283ad'	System	25 Aug 2020 19:47:41
User entered 'None (1)'	System	25 Aug 2020 19:47:41

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:47:33', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '192c695b-4bfa-419b-8a7e-efbb0b7283ad'	System	25 Aug 2020 19:47:41
User entered '25 Aug 2020 12:47'	System	25 Aug 2020 19:47:41

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 3'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:27:37', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bf422f84-1f7d-4bdd-b905-9750c768661b'	System	26 Aug 2020 19:28:08
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 19:28:08

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:27:42', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bf422f84-1f7d-4bdd-b905-9750c768661b'	System	26 Aug 2020 19:28:08
User entered 'No (N)'	System	26 Aug 2020 19:28:08

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:27:48', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bf422f84-1f7d-4bdd-b905-9750c768661b'	System	26 Aug 2020 19:28:08
User entered 'No (N)'	System	26 Aug 2020 19:28:08

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:27:56', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bf422f84-1f7d-4bdd-b905-9750c768661b'	System	26 Aug 2020 19:28:08
User entered 'None (1)'	System	26 Aug 2020 19:28:08

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:28:01', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bf422f84-1f7d-4bdd-b905-9750c768661b'	System	26 Aug 2020 19:28:08
User entered '26 Aug 2020 12:28'	System	26 Aug 2020 19:28:08

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 4'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T16:58:39', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '67edf5fa-6b1e-4ed4-b984-e8221b7b248c'	System	27 Aug 2020 23:59:08
User entered 'None (1)'	System	27 Aug 2020 23:59:08

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T16:58:42', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '67edf5fa-6b1e-4ed4-b984-e8221b7b248c'	System	27 Aug 2020 23:59:08
User entered 'No (N)'	System	27 Aug 2020 23:59:08

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T16:58:46', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '67edf5fa-6b1e-4ed4-b984-e8221b7b248c'	System	27 Aug 2020 23:59:08
User entered 'No (N)'	System	27 Aug 2020 23:59:08

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T16:58:54', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '67edf5fa-6b1e-4ed4-b984-e8221b7b248c'	System	27 Aug 2020 23:59:08
User entered 'None (1)'	System	27 Aug 2020 23:59:08

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T16:58:59', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '67edf5fa-6b1e-4ed4-b984-e8221b7b248c'	System	27 Aug 2020 23:59:08
User entered '27 Aug 2020 16:58'	System	27 Aug 2020 23:59:08

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 5'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:16:34', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '8ec77b80-2161-49ca-b2c9-e17a356cd886'	System	28 Aug 2020 23:16:59
User entered 'None (1)'	System	28 Aug 2020 23:16:59

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:16:38', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '8ec77b80-2161-49ca-b2c9-e17a356cd886'	System	28 Aug 2020 23:16:59
User entered 'No (N)'	System	28 Aug 2020 23:16:59

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:16:41', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '8ec77b80-2161-49ca-b2c9-e17a356cd886'	System	28 Aug 2020 23:16:59
User entered 'No (N)'	System	28 Aug 2020 23:16:59

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:16:48', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '8ec77b80-2161-49ca-b2c9-e17a356cd886'	System	28 Aug 2020 23:16:59
User entered 'None (1)'	System	28 Aug 2020 23:16:59

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:16:51', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '8ec77b80-2161-49ca-b2c9-e17a356cd886'	System	28 Aug 2020 23:16:59
User entered '28 Aug 2020 16:16'	System	28 Aug 2020 23:16:59

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 6'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:48:22', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '17a1fa9a-41cd-4301-9dd9-5d35985e5bc1'	System	29 Aug 2020 21:48:41
User entered 'None (1)'	System	29 Aug 2020 21:48:41

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:48:25', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '17a1fa9a-41cd-4301-9dd9-5d35985e5bc1'	System	29 Aug 2020 21:48:41
User entered 'No (N)'	System	29 Aug 2020 21:48:41

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:48:28', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '17a1fa9a-41cd-4301-9dd9-5d35985e5bc1'	System	29 Aug 2020 21:48:41
User entered 'No (N)'	System	29 Aug 2020 21:48:41

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:48:32', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '17a1fa9a-41cd-4301-9dd9-5d35985e5bc1'	System	29 Aug 2020 21:48:41
User entered 'None (1)'	System	29 Aug 2020 21:48:41

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:48:35', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '17a1fa9a-41cd-4301-9dd9-5d35985e5bc1'	System	29 Aug 2020 21:48:41
User entered '29 Aug 2020 14:48'	System	29 Aug 2020 21:48:41

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 7'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:03:08', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'c411cfc0-6ac3-42d0-8d74-c8498531abba'	System	30 Aug 2020 19:03:29
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 19:03:29

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:03:13', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'c411cfc0-6ac3-42d0-8d74-c8498531abba'	System	30 Aug 2020 19:03:29
User entered 'No (N)'	System	30 Aug 2020 19:03:29

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:03:16', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'c411cfc0-6ac3-42d0-8d74-c8498531abba'	System	30 Aug 2020 19:03:29
User entered 'No (N)'	System	30 Aug 2020 19:03:29

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:03:19', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'c411cfc0-6ac3-42d0-8d74-c8498531abba'	System	30 Aug 2020 19:03:29
User entered 'None (1)'	System	30 Aug 2020 19:03:29

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:03:23', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'c411cfc0-6ac3-42d0-8d74-c8498531abba'	System	30 Aug 2020 19:03:29
User entered '30 Aug 2020 12:03'	System	30 Aug 2020 19:03:29

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:45:52', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '704ff96c-c79f-46b8-afef-090bab8c01dd'	System	24 Aug 2020 21:46:37
User entered 'None (0)'	System	24 Aug 2020 21:46:37

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:45:56', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '704ff96c-c79f-46b8-afef-090bab8c01dd'	System	24 Aug 2020 21:46:37
User entered 'None (0)'	System	24 Aug 2020 21:46:37

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:46:02', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '704ff96c-c79f-46b8-afef-090bab8c01dd'	System	24 Aug 2020 21:46:37
User entered 'None (0)'	System	24 Aug 2020 21:46:37

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:46:09', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '704ff96c-c79f-46b8-afef-090bab8c01dd'	System	24 Aug 2020 21:46:37
User entered 'None (0)'	System	24 Aug 2020 21:46:37

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:46:13', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '704ff96c-c79f-46b8-afef-090bab8c01dd'	System	24 Aug 2020 21:46:37
User entered 'None (0)'	System	24 Aug 2020 21:46:37

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:46:16', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '704ff96c-c79f-46b8-afef-090bab8c01dd'	System	24 Aug 2020 21:46:37
User entered 'None (0)'	System	24 Aug 2020 21:46:37

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:46:21', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '704ff96c-c79f-46b8-afef-090bab8c01dd'	System	24 Aug 2020 21:46:37
User entered 'No (N)'	System	24 Aug 2020 21:46:37

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T14:46:29', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '704ff96c-c79f-46b8-afef-090bab8c01dd'	System	24 Aug 2020 21:46:37
User entered '24 Aug 2020 14:46'	System	24 Aug 2020 21:46:37

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '24 Aug 2020 14:33'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '24 Aug 2020 17:03'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:03:07', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1f742603-5725-467e-8b5c-b158baf98dc2'	System	25 Aug 2020 01:03:43
User entered 'None (0)'	System	25 Aug 2020 01:03:43

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:03:10', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1f742603-5725-467e-8b5c-b158baf98dc2'	System	25 Aug 2020 01:03:43
User entered 'None (0)'	System	25 Aug 2020 01:03:43

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:03:14', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1f742603-5725-467e-8b5c-b158baf98dc2'	System	25 Aug 2020 01:03:43
User entered 'None (0)'	System	25 Aug 2020 01:03:43

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:03:17', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1f742603-5725-467e-8b5c-b158baf98dc2'	System	25 Aug 2020 01:03:43
User entered 'None (0)'	System	25 Aug 2020 01:03:43

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:03:20', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1f742603-5725-467e-8b5c-b158baf98dc2'	System	25 Aug 2020 01:03:43
User entered 'None (0)'	System	25 Aug 2020 01:03:43

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:03:23', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1f742603-5725-467e-8b5c-b158baf98dc2'	System	25 Aug 2020 01:03:43
User entered 'None (0)'	System	25 Aug 2020 01:03:43

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:03:30', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1f742603-5725-467e-8b5c-b158baf98dc2'	System	25 Aug 2020 01:03:43
User entered 'No (N)'	System	25 Aug 2020 01:03:43

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-24T18:03:34', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1f742603-5725-467e-8b5c-b158baf98dc2'	System	25 Aug 2020 01:03:43
User entered '24 Aug 2020 18:03'	System	25 Aug 2020 01:03:43

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '24 Aug 2020 17:58'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 2'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:47:45', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'de435bc3-edc2-45e0-8d6b-5297d01e89ec'	System	25 Aug 2020 19:48:28
User entered 'None (0)'	System	25 Aug 2020 19:48:28

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:47:49', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'de435bc3-edc2-45e0-8d6b-5297d01e89ec'	System	25 Aug 2020 19:48:28
User entered 'None (0)'	System	25 Aug 2020 19:48:28

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:47:54', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'de435bc3-edc2-45e0-8d6b-5297d01e89ec'	System	25 Aug 2020 19:48:28
User entered 'None (0)'	System	25 Aug 2020 19:48:28

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:48:06', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'de435bc3-edc2-45e0-8d6b-5297d01e89ec'	System	25 Aug 2020 19:48:28
User entered 'None (0)'	System	25 Aug 2020 19:48:28

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:48:09', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'de435bc3-edc2-45e0-8d6b-5297d01e89ec'	System	25 Aug 2020 19:48:28
User entered 'None (0)'	System	25 Aug 2020 19:48:28

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:48:14', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'de435bc3-edc2-45e0-8d6b-5297d01e89ec'	System	25 Aug 2020 19:48:28
User entered 'None (0)'	System	25 Aug 2020 19:48:28

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:48:18', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'de435bc3-edc2-45e0-8d6b-5297d01e89ec'	System	25 Aug 2020 19:48:28
User entered 'No (N)'	System	25 Aug 2020 19:48:28

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-25T12:48:23', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'de435bc3-edc2-45e0-8d6b-5297d01e89ec'	System	25 Aug 2020 19:48:28
User entered '25 Aug 2020 12:48'	System	25 Aug 2020 19:48:28

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 3'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:28:45', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '71b1bcf9-b643-4d12-bc42-1fc38395f79f'	System	26 Aug 2020 19:29:59
User entered 'None (0)'	System	26 Aug 2020 19:29:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:28:49', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '71b1bcf9-b643-4d12-bc42-1fc38395f79f'	System	26 Aug 2020 19:29:59
User entered 'None (0)'	System	26 Aug 2020 19:29:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:28:53', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '71b1bcf9-b643-4d12-bc42-1fc38395f79f'	System	26 Aug 2020 19:29:59
User entered 'None (0)'	System	26 Aug 2020 19:29:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:28:58', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '71b1bcf9-b643-4d12-bc42-1fc38395f79f'	System	26 Aug 2020 19:29:59
User entered 'None (0)'	System	26 Aug 2020 19:29:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:29:44', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '71b1bcf9-b643-4d12-bc42-1fc38395f79f'	System	26 Aug 2020 19:29:59
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	26 Aug 2020 19:29:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:29:14', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '71b1bcf9-b643-4d12-bc42-1fc38395f79f'	System	26 Aug 2020 19:29:59
User entered 'None (0)'	System	26 Aug 2020 19:29:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:29:19', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '71b1bcf9-b643-4d12-bc42-1fc38395f79f'	System	26 Aug 2020 19:29:59
User entered 'No (N)'	System	26 Aug 2020 19:29:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-26T12:29:52', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '71b1bcf9-b643-4d12-bc42-1fc38395f79f'	System	26 Aug 2020 19:29:59
User entered '26 Aug 2020 12:29'	System	26 Aug 2020 19:29:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 4'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T16:59:05', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bacde13b-7bc2-444a-9dae-089c8af9efad'	System	28 Aug 2020 00:00:14
User entered 'None (0)'	System	28 Aug 2020 00:00:14

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T16:59:08', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bacde13b-7bc2-444a-9dae-089c8af9efad'	System	28 Aug 2020 00:00:14
User entered 'None (0)'	System	28 Aug 2020 00:00:14

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T16:59:12', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bacde13b-7bc2-444a-9dae-089c8af9efad'	System	28 Aug 2020 00:00:14
User entered 'None (0)'	System	28 Aug 2020 00:00:14

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T16:59:15', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bacde13b-7bc2-444a-9dae-089c8af9efad'	System	28 Aug 2020 00:00:14
User entered 'None (0)'	System	28 Aug 2020 00:00:14

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T16:59:34', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bacde13b-7bc2-444a-9dae-089c8af9efad'	System	28 Aug 2020 00:00:14
User entered 'None (0)'	System	28 Aug 2020 00:00:14

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T16:59:37', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bacde13b-7bc2-444a-9dae-089c8af9efad'	System	28 Aug 2020 00:00:14
User entered 'None (0)'	System	28 Aug 2020 00:00:14

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T16:59:40', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bacde13b-7bc2-444a-9dae-089c8af9efad'	System	28 Aug 2020 00:00:14
User entered 'No (N)'	System	28 Aug 2020 00:00:14

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-27T17:00:09', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bacde13b-7bc2-444a-9dae-089c8af9efad'	System	28 Aug 2020 00:00:14
User entered '27 Aug 2020 17:00'	System	28 Aug 2020 00:00:14

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 5'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:16:57', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'd99f5817-1a02-4e40-800d-bbcee7cea203'	System	28 Aug 2020 23:17:46
User entered 'None (0)'	System	28 Aug 2020 23:17:46

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:17:01', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'd99f5817-1a02-4e40-800d-bbcee7cea203'	System	28 Aug 2020 23:17:46
User entered 'None (0)'	System	28 Aug 2020 23:17:46

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:17:05', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'd99f5817-1a02-4e40-800d-bbcee7cea203'	System	28 Aug 2020 23:17:46
User entered 'None (0)'	System	28 Aug 2020 23:17:46

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:17:08', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'd99f5817-1a02-4e40-800d-bbcee7cea203'	System	28 Aug 2020 23:17:46
User entered 'None (0)'	System	28 Aug 2020 23:17:46

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:17:11', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'd99f5817-1a02-4e40-800d-bbcee7cea203'	System	28 Aug 2020 23:17:46
User entered 'None (0)'	System	28 Aug 2020 23:17:46

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:17:14', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'd99f5817-1a02-4e40-800d-bbcee7cea203'	System	28 Aug 2020 23:17:46
User entered 'None (0)'	System	28 Aug 2020 23:17:46

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:17:18', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'd99f5817-1a02-4e40-800d-bbcee7cea203'	System	28 Aug 2020 23:17:46
User entered 'Yes (Y)'	System	28 Aug 2020 23:17:46

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-28T16:17:38', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'd99f5817-1a02-4e40-800d-bbcee7cea203'	System	28 Aug 2020 23:17:46
User entered '28 Aug 2020 16:17'	System	28 Aug 2020 23:17:46

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 6'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:48:40', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '4ea2dba1-9ff0-4723-b2ca-671a39b65456'	System	29 Aug 2020 21:49:19
User entered 'None (0)'	System	29 Aug 2020 21:49:19

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:48:43', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '4ea2dba1-9ff0-4723-b2ca-671a39b65456'	System	29 Aug 2020 21:49:19
User entered 'None (0)'	System	29 Aug 2020 21:49:19

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:48:47', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '4ea2dba1-9ff0-4723-b2ca-671a39b65456'	System	29 Aug 2020 21:49:19
User entered 'None (0)'	System	29 Aug 2020 21:49:19

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:48:50', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '4ea2dba1-9ff0-4723-b2ca-671a39b65456'	System	29 Aug 2020 21:49:19
User entered 'None (0)'	System	29 Aug 2020 21:49:19

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:48:53', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '4ea2dba1-9ff0-4723-b2ca-671a39b65456'	System	29 Aug 2020 21:49:19
User entered 'None (0)'	System	29 Aug 2020 21:49:19

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:48:55', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '4ea2dba1-9ff0-4723-b2ca-671a39b65456'	System	29 Aug 2020 21:49:19
User entered 'None (0)'	System	29 Aug 2020 21:49:19

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:49:02', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '4ea2dba1-9ff0-4723-b2ca-671a39b65456'	System	29 Aug 2020 21:49:19
User entered 'No (N)'	System	29 Aug 2020 21:49:19

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-29T14:49:14', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '4ea2dba1-9ff0-4723-b2ca-671a39b65456'	System	29 Aug 2020 21:49:19
User entered '29 Aug 2020 14:49'	System	29 Aug 2020 21:49:19

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	24 Aug 2020 21:13:52
User entered 'Day 7'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:03:29', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f83eb0b0-cf5e-496f-bedf-782c92517622'	System	30 Aug 2020 19:03:59
User entered 'None (0)'	System	30 Aug 2020 19:03:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:03:32', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f83eb0b0-cf5e-496f-bedf-782c92517622'	System	30 Aug 2020 19:03:59
User entered 'None (0)'	System	30 Aug 2020 19:03:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:03:34', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f83eb0b0-cf5e-496f-bedf-782c92517622'	System	30 Aug 2020 19:03:59
User entered 'None (0)'	System	30 Aug 2020 19:03:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:03:36', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f83eb0b0-cf5e-496f-bedf-782c92517622'	System	30 Aug 2020 19:03:59
User entered 'None (0)'	System	30 Aug 2020 19:03:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:03:39', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f83eb0b0-cf5e-496f-bedf-782c92517622'	System	30 Aug 2020 19:03:59
User entered 'None (0)'	System	30 Aug 2020 19:03:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:03:41', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f83eb0b0-cf5e-496f-bedf-782c92517622'	System	30 Aug 2020 19:03:59
User entered 'None (0)'	System	30 Aug 2020 19:03:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:03:46', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f83eb0b0-cf5e-496f-bedf-782c92517622'	System	30 Aug 2020 19:03:59
User entered 'No (N)'	System	30 Aug 2020 19:03:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-30T12:03:50', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'f83eb0b0-cf5e-496f-bedf-782c92517622'	System	30 Aug 2020 19:03:59
User entered '30 Aug 2020 12:03'	System	30 Aug 2020 19:03:59

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 21:13:52

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	30 Aug 2020 19:03:29
User entered 'Day 8'	System	30 Aug 2020 19:03:29

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:23:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-31T12:02:20', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b0935642-792b-4012-9f07-3d20e616cc1e'	System	31 Aug 2020 19:06:01
User entered 'None (1)'	System	31 Aug 2020 19:06:01

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:23:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-31T12:02:25', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b0935642-792b-4012-9f07-3d20e616cc1e'	System	31 Aug 2020 19:06:01
User entered '31 Aug 2020 12:02'	System	31 Aug 2020 19:06:01

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 19:03:29

US3162003

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 19:03:29

US3162003

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	30 Aug 2020 19:03:06
User entered 'Day 8'	System	30 Aug 2020 19:03:06

US3162003

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:23:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-31T12:02:32', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '689109b9-7bb0-4a29-883a-e1da9bcaa72b'	System	31 Aug 2020 19:06:15
User entered 'No (N)'	System	31 Aug 2020 19:06:15

US3162003

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:23:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-08-31T12:02:36', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '689109b9-7bb0-4a29-883a-e1da9bcaa72b'	System	31 Aug 2020 19:06:15
User entered '31 Aug 2020 12:02'	System	31 Aug 2020 19:06:15

US3162003

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:23:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 19:03:06

US3162003

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:23:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 19:03:06

US3162003

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:47:38
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:03:33

US3162003

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:47:38
User entered '31 Aug 2020'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:03:33

US3162003

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:47:38
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:03:33

US3162003

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:47:38
User entered empty.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:03:33

US3162003

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:47:48
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:03:39

US3162003

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User entered 'I'	System	03 Sep 2020 19:03:39

US3162003

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:48:34
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:15:17

US3162003

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:48:34
User entered '07 Sep 2020'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:15:17

US3162003

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:48:34
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:15:17

US3162003

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:48:34
User entered empty.	Cynthia Kunakom (b) (4)	08 Sep 2020 19:15:17

US3162003

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:48:41
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:16:05

US3162003

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User entered 'I'	System	08 Sep 2020 19:16:05

US3162003

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:49:04
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	15 Sep 2020 17:26:54

US3162003

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:49:04
User entered '14 Sep 2020'	Cynthia Kunakom (b) (4)	15 Sep 2020 17:26:54

US3162003

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:49:04
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4)	15 Sep 2020 17:26:54

US3162003

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:49:04
User entered empty.	Cynthia Kunakom (b) (4)	15 Sep 2020 17:26:54

US3162003

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 08:24:31
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	15 Sep 2020 17:26:58

US3162003

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User entered 'I'	System	15 Sep 2020 17:26:58

US3162003

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:12
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	22 Sep 2020 03:47:24

US3162003

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:15
User entered '21 Sep 2020'	Jared Bradshaw (b) (4)	22 Sep 2020 03:47:24

US3162003

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[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 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:15
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4)	22 Sep 2020 03:47:24

US3162003

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'VISIT3'	System	22 Sep 2020 03:47:24

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User closed query 'Per CDM: Vital signs is performed on 21 Sep 2020 for Visit 3 Day 57 as well as Illness Visit Day 1 , kindly review if they are duplicates else clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 04:49:52
Query 'Per CDM: Vital signs is performed on 21 Sep 2020 for Visit 3 Day 57 as well as Illness Visit Day 1 , kindly review if they are duplicates else clarify.' answered with 'Subject came for Visit 3, but was having symptoms of illness, so illness day 1 visit done same day, and same VS were used in both visits.' (Site from DM).	Judith Kirstein (b) (4)	20 Feb 2021 06:36:42
User opened query 'Per CDM: Vital signs is performed on 21 Sep 2020 for Visit 3 Day 57 as well as Illness Visit Day 1 , kindly review if they are duplicates else clarify.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 15:08:39
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:08:10
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:01

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:08:10
User entered '21 Sep 2020'	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:01

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:08:10
User entered '11:23'	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:01

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered '21 Sep 2020 11:23'	System	22 Sep 2020 03:48:01

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:08:10
User entered '97.4' F	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:01

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:08:10
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:01

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:08:10
User entered empty.	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:01

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:08:10
User entered '66'	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:01

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'bpm'	System	22 Sep 2020 03:48:01

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:08:10
User entered '16'	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:01

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'breaths/min'	System	22 Sep 2020 03:48:01

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:08:10
User entered '137'	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:01

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'mmHg'	System	22 Sep 2020 03:48:01

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:08:10
User entered '69'	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:01

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'mmHg'	System	22 Sep 2020 03:48:01

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22

US3162003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22

US3162003

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:27

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:27
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	22 Sep 2020 03:48:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:27
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	22 Sep 2020 03:48:07
User entered 'No (N)'	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:07

US3162003

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:28
User entered '21 Sep 2020'	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:07

US3162003

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:50:40
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:39

US3162003

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:50:40
User entered '21 Sep 2020'	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:39

US3162003

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:50:40
User entered '11:50'	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:39

US3162003

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered '21 Sep 2020 11:50'	System	22 Sep 2020 03:48:39

US3162003

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 07:03:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	22 Sep 2020 03:48:43

US3162003

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:22
User entered 'I'	System	22 Sep 2020 03:48:43

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 64'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-09-26T07:59:20', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e88a1075-9e59-4908-b716-107fae2e3bfe'	System	26 Sep 2020 14:59:36
User entered 'No (N)'	System	26 Sep 2020 14:59:36

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-09-26T07:59:24', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e88a1075-9e59-4908-b716-107fae2e3bfe'	System	26 Sep 2020 14:59:36
User entered 'No (N)'	System	26 Sep 2020 14:59:36

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-09-26T07:59:30', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e88a1075-9e59-4908-b716-107fae2e3bfe'	System	26 Sep 2020 14:59:36
User entered '26 Sep 2020 07:59:30'	System	26 Sep 2020 14:59:36

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered '26 Sep 2020 00:01'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered '30 Sep 2020 23:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 71'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-10-03T08:31:28', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '23bb8185-f9f9-46af-bc9a-477c5bd14407'	System	03 Oct 2020 15:31:54
User entered 'No (N)'	System	03 Oct 2020 15:31:54

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-10-03T08:31:34', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '23bb8185-f9f9-46af-bc9a-477c5bd14407'	System	03 Oct 2020 15:31:54
User entered 'No (N)'	System	03 Oct 2020 15:31:54

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-10-03T08:31:45', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '23bb8185-f9f9-46af-bc9a-477c5bd14407'	System	03 Oct 2020 15:31:54
User entered '03 Oct 2020 08:31:45'	System	03 Oct 2020 15:31:54

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered '03 Oct 2020 00:01'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered '07 Oct 2020 23:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 78'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-10-12T12:31:01', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '95b5105b-1218-4c1b-a7d1-6b6272bb3dbc'	System	12 Oct 2020 19:31:13
User entered 'No (N)'	System	12 Oct 2020 19:31:13

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-10-12T12:31:04', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '95b5105b-1218-4c1b-a7d1-6b6272bb3dbc'	System	12 Oct 2020 19:31:13
User entered 'No (N)'	System	12 Oct 2020 19:31:13

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-10-12T12:31:08', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '95b5105b-1218-4c1b-a7d1-6b6272bb3dbc'	System	12 Oct 2020 19:31:13
User entered '12 Oct 2020 12:31:08'	System	12 Oct 2020 19:31:13

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered '10 Oct 2020 00:01'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered '14 Oct 2020 23:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 92'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-10-24T07:15:20', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'd8f77147-b11d-4b1c-bf4b-f137fdeb19b0'	System	24 Oct 2020 14:15:44
User entered 'No (N)'	System	24 Oct 2020 14:15:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-10-24T07:15:33', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'd8f77147-b11d-4b1c-bf4b-f137fdeb19b0'	System	24 Oct 2020 14:15:44
User entered 'No (N)'	System	24 Oct 2020 14:15:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-10-24T07:15:41', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'd8f77147-b11d-4b1c-bf4b-f137fdeb19b0'	System	24 Oct 2020 14:15:44
User entered '24 Oct 2020 07:15:41'	System	24 Oct 2020 14:15:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered '24 Oct 2020 00:01'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered '28 Oct 2020 23:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 99'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-10-31T07:10:04', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '74b5381c-06b1-4665-89dc-e1601b0ad4eb'	System	31 Oct 2020 14:10:32
User entered 'No (N)'	System	31 Oct 2020 14:10:32

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-10-31T07:10:09', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '74b5381c-06b1-4665-89dc-e1601b0ad4eb'	System	31 Oct 2020 14:10:32
User entered 'No (N)'	System	31 Oct 2020 14:10:32

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-10-31T07:10:28', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '74b5381c-06b1-4665-89dc-e1601b0ad4eb'	System	31 Oct 2020 14:10:32
User entered '31 Oct 2020 07:10:28'	System	31 Oct 2020 14:10:32

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered '31 Oct 2020 00:01'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered '04 Nov 2020 23:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 106'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-11-09T09:04:10', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'a0fc5944-b4ef-49de-8924-ecbfb99c4374'	System	09 Nov 2020 17:06:14
User entered 'No (N)'	System	09 Nov 2020 17:06:14

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-11-09T09:04:15', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'a0fc5944-b4ef-49de-8924-ecbfb99c4374'	System	09 Nov 2020 17:06:14
User entered 'No (N)'	System	09 Nov 2020 17:06:14

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-11-09T09:04:20', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'a0fc5944-b4ef-49de-8924-ecbfb99c4374'	System	09 Nov 2020 17:06:14
User entered '09 Nov 2020 09:04:20'	System	09 Nov 2020 17:06:14

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered '07 Nov 2020 00:01'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered '11 Nov 2020 23:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered 'Day 113'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-11-14T12:02:04', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'ec9dbd4b-a04e-4544-bc59-cb66364b72aa'	System	14 Nov 2020 20:02:18
User entered 'No (N)'	System	14 Nov 2020 20:02:18

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-11-14T12:02:09', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'ec9dbd4b-a04e-4544-bc59-cb66364b72aa'	System	14 Nov 2020 20:02:18
User entered 'No (N)'	System	14 Nov 2020 20:02:18

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-11-14T12:02:13', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'ec9dbd4b-a04e-4544-bc59-cb66364b72aa'	System	14 Nov 2020 20:02:18
User entered '14 Nov 2020 12:02:13'	System	14 Nov 2020 20:02:18

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered '14 Nov 2020 00:01'	System	28 Jul 2020 00:27:44

US3162003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:14
Data entry locked.	System	28 Jul 2020 00:27:44
User entered '18 Nov 2020 23:59'	System	28 Jul 2020 00:27:44

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-11-18T19:03:43', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'cd5b8901-81e9-45a4-9dc2-519c4b7623c7'	System	19 Nov 2020 03:04:03
User entered 'No (N)'	System	19 Nov 2020 03:04:03

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-11-18T19:03:49', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'cd5b8901-81e9-45a4-9dc2-519c4b7623c7'	System	19 Nov 2020 03:04:03
User entered 'No (N)'	System	19 Nov 2020 03:04:03

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-11-18T19:03:58', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'cd5b8901-81e9-45a4-9dc2-519c4b7623c7'	System	19 Nov 2020 03:04:03
User entered '18 Nov 2020 19:03:58'	System	19 Nov 2020 03:04:03

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-11-27T13:30:36', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '566a717d-714c-4507-b228-c3c60edca664'	System	27 Nov 2020 21:30:46
User entered 'No (N)'	System	27 Nov 2020 21:30:46

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-11-27T13:30:39', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '566a717d-714c-4507-b228-c3c60edca664'	System	27 Nov 2020 21:30:46
User entered 'No (N)'	System	27 Nov 2020 21:30:46

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-11-27T13:30:42', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '566a717d-714c-4507-b228-c3c60edca664'	System	27 Nov 2020 21:30:46
User entered '27 Nov 2020 13:30:42'	System	27 Nov 2020 21:30:46

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-12-02T07:05:49', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '8f578bfc-4d6f-41f4-9a8b-f72efc351678'	System	02 Dec 2020 15:06:02
User entered 'No (N)'	System	02 Dec 2020 15:06:02

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-12-02T07:05:52', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '8f578bfc-4d6f-41f4-9a8b-f72efc351678'	System	02 Dec 2020 15:06:02
User entered 'No (N)'	System	02 Dec 2020 15:06:02

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-12-02T07:05:57', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '8f578bfc-4d6f-41f4-9a8b-f72efc351678'	System	02 Dec 2020 15:06:02
User entered '02 Dec 2020 07:05:57'	System	02 Dec 2020 15:06:02

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-12-09T18:35:07', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b1f2a9f7-9bc0-479c-934f-b68105ee3581'	System	10 Dec 2020 02:35:24
User entered 'No (N)'	System	10 Dec 2020 02:35:24

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-12-09T18:35:15', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b1f2a9f7-9bc0-479c-934f-b68105ee3581'	System	10 Dec 2020 02:35:24
User entered 'No (N)'	System	10 Dec 2020 02:35:24

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-12-09T18:35:19', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b1f2a9f7-9bc0-479c-934f-b68105ee3581'	System	10 Dec 2020 02:35:24
User entered '09 Dec 2020 18:35:19'	System	10 Dec 2020 02:35:24

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-12-16T08:38:29', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '0299572d-2234-4df9-89b4-e9b6c6a0c6dc'	System	16 Dec 2020 16:38:47
User entered 'No (N)'	System	16 Dec 2020 16:38:47

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-12-16T08:38:37', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '0299572d-2234-4df9-89b4-e9b6c6a0c6dc'	System	16 Dec 2020 16:38:47
User entered 'No (N)'	System	16 Dec 2020 16:38:47

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-12-16T08:38:42', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '0299572d-2234-4df9-89b4-e9b6c6a0c6dc' User entered '16 Dec 2020 08:38:42'	System	16 Dec 2020 16:38:47
	System	16 Dec 2020 16:38:47

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-12-23T19:37:40', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'dfa3c78f-2b36-4221-b048-72a8f596a596'	System	24 Dec 2020 03:38:11
User entered 'No (N)'	System	24 Dec 2020 03:38:11

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-12-23T19:37:58', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'dfa3c78f-2b36-4221-b048-72a8f596a596'	System	24 Dec 2020 03:38:11
User entered 'No (N)'	System	24 Dec 2020 03:38:11

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-12-23T19:38:04', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'dfa3c78f-2b36-4221-b048-72a8f596a596'	System	24 Dec 2020 03:38:11
User entered '23 Dec 2020 19:38:04'	System	24 Dec 2020 03:38:11

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-12-30T06:03:51', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '8db18d18-2cd2-478b-a46b-b958cce2ce31'	System	30 Dec 2020 14:04:22
User entered 'No (N)'	System	30 Dec 2020 14:04:22

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-12-30T06:04:04', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '8db18d18-2cd2-478b-a46b-b958cce2ce31'	System	30 Dec 2020 14:04:22
User entered 'No (N)'	System	30 Dec 2020 14:04:22

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2020-12-30T06:04:17', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '8db18d18-2cd2-478b-a46b-b958cce2ce31'	System	30 Dec 2020 14:04:22
User entered '30 Dec 2020 06:04:17'	System	30 Dec 2020 14:04:22

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-01-06T12:02:24', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b8a6c6fc-669b-4c45-89cc-5f625a4626f2'	System	06 Jan 2021 20:02:48
User entered 'No (N)'	System	06 Jan 2021 20:02:48

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-01-06T12:02:31', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b8a6c6fc-669b-4c45-89cc-5f625a4626f2'	System	06 Jan 2021 20:02:48
User entered 'No (N)'	System	06 Jan 2021 20:02:48

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-01-06T12:02:42', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'b8a6c6fc-669b-4c45-89cc-5f625a4626f2' User entered '06 Jan 2021 12:02:42'	System	06 Jan 2021 20:02:48
	System	06 Jan 2021 20:02:48

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-01-13T12:24:30', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bdf21348-0d60-4211-99df-2d2030f68625'	System	13 Jan 2021 20:24:43
User entered 'No (N)'	System	13 Jan 2021 20:24:43

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-01-13T12:24:33', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bdf21348-0d60-4211-99df-2d2030f68625'	System	13 Jan 2021 20:24:43
User entered 'No (N)'	System	13 Jan 2021 20:24:43

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-01-13T12:24:39', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'bdf21348-0d60-4211-99df-2d2030f68625'	System	13 Jan 2021 20:24:43
User entered '13 Jan 2021 12:24:39'	System	13 Jan 2021 20:24:43

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-01-20T07:03:24', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '043f373e-fabe-4200-be44-4f1d615673a0'	System	20 Jan 2021 15:03:48
User entered 'No (N)'	System	20 Jan 2021 15:03:48

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-01-20T07:03:37', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '043f373e-fabe-4200-be44-4f1d615673a0'	System	20 Jan 2021 15:03:48
User entered 'No (N)'	System	20 Jan 2021 15:03:48

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-01-20T07:03:44', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '043f373e-fabe-4200-be44-4f1d615673a0' User entered '20 Jan 2021 07:03:44'	System	20 Jan 2021 15:03:48
	System	20 Jan 2021 15:03:48

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-01-27T18:27:58', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'ac05aae5-47d1-467d-8ebb-d52049c9d00a'	System	28 Jan 2021 02:28:19
User entered 'No (N)'	System	28 Jan 2021 02:28:19

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-01-27T18:28:04', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'ac05aae5-47d1-467d-8ebb-d52049c9d00a'	System	28 Jan 2021 02:28:19
User entered 'No (N)'	System	28 Jan 2021 02:28:19

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-01-27T18:28:16', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'ac05aae5-47d1-467d-8ebb-d52049c9d00a'	System	28 Jan 2021 02:28:19
User entered '27 Jan 2021 18:28:16'	System	28 Jan 2021 02:28:19

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-02-03T13:29:51', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'afb45d92-fa71-4ed5-a4ce-4b352df623ce'	System	03 Feb 2021 21:30:19
User entered 'No (N)'	System	03 Feb 2021 21:30:19

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-02-03T13:30:02', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'afb45d92-fa71-4ed5-a4ce-4b352df623ce'	System	03 Feb 2021 21:30:19
User entered 'No (N)'	System	03 Feb 2021 21:30:19

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-02-03T13:30:11', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'afb45d92-fa71-4ed5-a4ce-4b352df623ce'	System	03 Feb 2021 21:30:19
User entered '03 Feb 2021 13:30:11'	System	03 Feb 2021 21:30:19

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-02-24T13:56:45', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '90e992b5-c233-403d-8c8f-d6b3b5f9e22c'	System	24 Feb 2021 21:59:45
User entered 'No (N)'	System	24 Feb 2021 21:59:45

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-02-24T13:56:50', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '90e992b5-c233-403d-8c8f-d6b3b5f9e22c'	System	24 Feb 2021 21:59:45
User entered 'No (N)'	System	24 Feb 2021 21:59:45

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-02-24T13:56:56', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '90e992b5-c233-403d-8c8f-d6b3b5f9e22c'	System	24 Feb 2021 21:59:45
User entered '24 Feb 2021 13:56:56'	System	24 Feb 2021 21:59:45

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-03T06:33:15', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1901b85d-bc73-4a19-b9a9-becdb6b0ffce'	System	03 Mar 2021 14:33:29
User entered 'No (N)'	System	03 Mar 2021 14:33:29

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-03T06:30:29', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1901b85d-bc73-4a19-b9a9-becdb6b0ffce'	System	03 Mar 2021 14:33:29
User entered 'No (N)'	System	03 Mar 2021 14:33:29

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-03T06:33:25', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1901b85d-bc73-4a19-b9a9-becdb6b0ffce' User entered '03 Mar 2021 06:33:25'	System	03 Mar 2021 14:33:29
	System	03 Mar 2021 14:33:29

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-12T08:31:47-08:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '3a79c704-c693-4dc7-92bd-064c697604db'	System	12 Mar 2021 16:31:57
User entered 'No (N)'	System	12 Mar 2021 16:31:57

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-12T08:31:49-08:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '3a79c704-c693-4dc7-92bd-064c697604db'	System	12 Mar 2021 16:31:57
User entered 'No (N)'	System	12 Mar 2021 16:31:57

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-12T08:31:52-08:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '3a79c704-c693-4dc7-92bd-064c697604db' User entered '12 Mar 2021 08:31:52'	System	12 Mar 2021 16:31:57
	System	12 Mar 2021 16:31:57

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-18T09:49:19-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'c52ff084-dcad-4d20-afdf-ea676e4330d6'	System	18 Mar 2021 16:49:41
User entered 'No (N)'	System	18 Mar 2021 16:49:41

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-18T09:49:31-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'c52ff084-dcad-4d20-afdf-ea676e4330d6'	System	18 Mar 2021 16:49:41
User entered 'No (N)'	System	18 Mar 2021 16:49:41

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-18T09:49:34-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'c52ff084-dcad-4d20-afdf-ea676e4330d6'	System	18 Mar 2021 16:49:41
User entered '18 Mar 2021 09:49:34'	System	18 Mar 2021 16:49:41

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-24T15:59:07-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '9a46584c-bd7f-40d9-ba06-a145436df15b'	System	24 Mar 2021 22:59:30
User entered 'No (N)'	System	24 Mar 2021 22:59:30

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-24T15:59:09-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '9a46584c-bd7f-40d9-ba06-a145436df15b'	System	24 Mar 2021 22:59:30
User entered 'No (N)'	System	24 Mar 2021 22:59:30

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-24T15:59:24-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '9a46584c-bd7f-40d9-ba06-a145436df15b'	System	24 Mar 2021 22:59:30
User entered '24 Mar 2021 15:59:24'	System	24 Mar 2021 22:59:30

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-31T12:24:09-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e4586a08-0eec-4b85-84a1-6b00db9ccb9f'	System	31 Mar 2021 19:24:26
User entered 'No (N)'	System	31 Mar 2021 19:24:26

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-31T12:24:12-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e4586a08-0eec-4b85-84a1-6b00db9ccb9f'	System	31 Mar 2021 19:24:26
User entered 'No (N)'	System	31 Mar 2021 19:24:26

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-31T12:24:20-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: 'e4586a08-0eec-4b85-84a1-6b00db9ccb9f' User entered '31 Mar 2021 12:24:20'	System	31 Mar 2021 19:24:26
	System	31 Mar 2021 19:24:26

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-04-07T07:05:11-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1270a064-4626-4fc4-a2eb-3ed48c5f65a9' User entered 'No (N)'	System	07 Apr 2021 14:05:23
	System	07 Apr 2021 14:05:23

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-04-07T07:05:15-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1270a064-4626-4fc4-a2eb-3ed48c5f65a9'	System	07 Apr 2021 14:05:23
User entered 'No (N)'	System	07 Apr 2021 14:05:23

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-04-07T07:05:19-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '1270a064-4626-4fc4-a2eb-3ed48c5f65a9'	System	07 Apr 2021 14:05:23
User entered '07 Apr 2021 07:05:19'	System	07 Apr 2021 14:05:23

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-04-14T06:16:02-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '61a5481f-1c01-4f69-9700-d699abd08380'	System	14 Apr 2021 13:16:27
User entered 'No (N)'	System	14 Apr 2021 13:16:27

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-04-14T06:16:05-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '61a5481f-1c01-4f69-9700-d699abd08380'	System	14 Apr 2021 13:16:27
User entered 'No (N)'	System	14 Apr 2021 13:16:27

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-04-14T06:16:23-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '61a5481f-1c01-4f69-9700-d699abd08380' User entered '14 Apr 2021 06:16:23'	System	14 Apr 2021 13:16:27
	System	14 Apr 2021 13:16:27

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-04-21T08:06:53-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '492cbaac-0d72-4566-8cb6-d208a4b0fc22'	System	21 Apr 2021 15:07:06
User entered 'No (N)'	System	21 Apr 2021 15:07:06

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-04-21T08:06:55-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '492cbaac-0d72-4566-8cb6-d208a4b0fc22'	System	21 Apr 2021 15:07:06
User entered 'No (N)'	System	21 Apr 2021 15:07:06

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-04-21T08:07:02-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '492cbaac-0d72-4566-8cb6-d208a4b0fc22'	System	21 Apr 2021 15:07:06
User entered '21 Apr 2021 08:07:02'	System	21 Apr 2021 15:07:06

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-04-29T19:06:04-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '3b4762ce-4861-4ecd-82f6-a252155cd234'	System	30 Apr 2021 02:10:45
User entered 'No (N)'	System	30 Apr 2021 02:10:45

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-04-29T19:06:13-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '3b4762ce-4861-4ecd-82f6-a252155cd234'	System	30 Apr 2021 02:10:45
User entered 'No (N)'	System	30 Apr 2021 02:10:45

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-04-29T19:06:24-07:00', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '3b4762ce-4861-4ecd-82f6-a252155cd234'	System	30 Apr 2021 02:10:45
User entered '29 Apr 2021 19:06:24'	System	30 Apr 2021 02:10:45

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 02:13:54

US3162003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:54
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 02:13:54

US3162003

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:23:27

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)	25 Apr 2021 17:31:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-03T06:33:37', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '22c17db4-16a2-4946-b3c3-a886c80c0ef2'	System	03 Mar 2021 14:33:51
User entered 'No (N)'	System	03 Mar 2021 14:33:51

US3162003

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:23:27

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:31:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1e4a792d7a4f383)', Time: '2021-03-03T06:33:45', User OID: 'PatientReportedOutcome (US3162003)', ODM File OID: '22c17db4-16a2-4946-b3c3-a886c80c0ef2'	System	03 Mar 2021 14:33:51
User entered '03 Mar 2021 06:33:45'	System	03 Mar 2021 14:33:51

US3162003

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:23:31
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:36

US3162003

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:40:27
User closed query 'Please review date of contact against source.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 00:40:24
Query 'Please review date of contact against source.' answered with 'Corrected date' (Site from CRA).	Judith Kirstein (b) (4)	10 Nov 2020 23:04:31
User entered '19 Oct 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	10 Nov 2020 23:04:21
User opened query 'Please review date of contact against source.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:23:28
User entered '20 Oct 2020'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:36

US3162003

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:23:33
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:36

US3162003

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:23:35
User entered empty.	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:36

US3162003

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:28:39
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:47

US3162003

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:11
User entered 'I'	System	20 Oct 2020 15:27:47

US3162003

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:45:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 19:34:59

US3162003

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:45:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered '23 Nov 2020'	(b) (4), (b) (6)	24 Nov 2020 19:34:59

US3162003

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:45:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Nov 2020 19:34:59

US3162003

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:45:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:34:59

US3162003

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:45:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 19:35:08

US3162003

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
User entered 'I'	System	24 Nov 2020 19:35:08

US3162003

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:47:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	23 Dec 2020 00:14:13

US3162003

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:47:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered '21 Dec 2020'	Tiffany Williams (b) (4)	23 Dec 2020 00:14:13

US3162003

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:47:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	23 Dec 2020 00:14:13

US3162003

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:47:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered empty.	Tiffany Williams (b) (4)	23 Dec 2020 00:14:13

US3162003

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:47:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	23 Dec 2020 00:14:20

US3162003

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
User entered 'I'	System	23 Dec 2020 00:14:20

US3162003

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:49:02
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	27 Jan 2021 17:40:54

US3162003

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:49:02
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered '22 Jan 2021'	Tiffany Williams (b) (4)	27 Jan 2021 17:40:54

US3162003

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:49:02
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	27 Jan 2021 17:40:54

US3162003

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:49:02
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered empty.	Tiffany Williams (b) (4)	27 Jan 2021 17:40:54

US3162003

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:51:29
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	27 Jan 2021 17:41:00

US3162003

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:45
User entered 'I'	System	27 Jan 2021 17:41:00

US3162003

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:36:27
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	22 Feb 2021 17:27:20

US3162003

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:36:27
User entered '19 Feb 2021'	Tiffany Williams (b) (4)	22 Feb 2021 17:27:20

US3162003

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:36:27
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4)	22 Feb 2021 17:27:20

US3162003

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'VISIT4'	System	22 Feb 2021 17:27:20

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:05:40
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:33:29

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:05:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:33:29

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:05:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:33:29

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered empty.	System	30 Mar 2021 18:33:29

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:05:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:33:29

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:05:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:33:29

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:05:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:33:29

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:05:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:33:29

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered empty.	System	30 Mar 2021 18:33:29

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:05:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:33:29

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered empty.	System	30 Mar 2021 18:33:29

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:05:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:33:29

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered empty.	System	30 Mar 2021 18:33:29

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:05:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:33:29

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered empty.	System	30 Mar 2021 18:33:29

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33

US3162003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33

US3162003

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:27

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
User closed query 'Please complete Immunogenicity Assessment eCRF page. ' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 00:39:23
Query 'Please complete Immunogenicity Assessment eCRF page. ' answered with 'Done.' (Site from CRA).	Marcia Bernard (b) (4)	02 Mar 2021 22:42:20
User opened query 'Please complete Immunogenicity Assessment eCRF page. ' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:38:54
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:33
User entered 'No (N)'	Tiffany Williams (b) (4)	22 Feb 2021 17:27:30

US3162003

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:33
User entered empty.	Tiffany Williams (b) (4)	22 Feb 2021 17:27:30

US3162003

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:41:21
User entered 'Yes (Y)'	Marcia Bernard (b) (4)	02 Mar 2021 22:42:02

US3162003

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:41:21
User entered '19 Feb 2021'	Marcia Bernard (b) (4)	02 Mar 2021 22:42:02

US3162003

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:41:21
User entered '10:02'	Marcia Bernard (b) (4)	02 Mar 2021 22:42:02

US3162003

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered '19 Feb 2021 10:02'	System	02 Mar 2021 22:42:02

US3162003

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:38:57
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	22 Feb 2021 17:27:41

US3162003

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:33
User entered 'I'	System	22 Feb 2021 17:27:41

US3162003

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:46:29
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	23 Mar 2021 22:27:27

US3162003

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:46:29
User entered '22 Mar 2021'	Tiffany Williams (b) (4)	23 Mar 2021 22:27:27

US3162003

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:46:29
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	23 Mar 2021 22:27:27

US3162003

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:46:29
User entered empty.	Tiffany Williams (b) (4)	23 Mar 2021 22:27:27

US3162003

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:46:36
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	23 Mar 2021 22:27:58

US3162003

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:54
User entered 'I'	System	23 Mar 2021 22:27:58

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:23:27

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:45:26
User entered '21 Sep 2020'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:47:48

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:23:27

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:45:26
User entered '12:36'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:47:48

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:23:27

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User entered '21 Sep 2020 12:36'	System	23 Sep 2020 14:47:48

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:23:27

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:45:26
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:47:48

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:23:27

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:45:26
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:47:48

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:51
User entered 'Day 1 (Day 1)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User closed query 'Per CDM: it appears both contact date and symptom start date are the same. Please confirm this date is the actual symptom start date and update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:43:59
Query 'Per CDM: it appears both contact date and symptom start date are the same. Please confirm this date is the actual symptom start date and update accordingly.' answered with 'First symptom was on 11Sep20. Subject first mentioned the shortness of breath during 21Sep20 visit. Assessment completed was for 21Sep20.' (Site from DM).	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:14
User opened query 'Per CDM: it appears both contact date and symptom start date are the same. Please confirm this date is the actual symptom start date and update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:40:01
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered '21 Sep 2020'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered '0'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered '90'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User entered '%'	System	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User closed query 'Per CDM: it appears the temperature appears rather high. Please reconcile' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:50:13
Query 'Per CDM: it appears the temperature appears rather high. Please reconcile' answered with 'Updated' (Site from DM).	Judith Kirstein (b) (4)	12 Nov 2020 03:01:18
DataPoint Un-verified.	Judith Kirstein (b) (4)	12 Nov 2020 03:01:05
User entered '36.3' C reason for change: Data Entry Error	Judith Kirstein (b) (4)	12 Nov 2020 03:01:05
User opened query 'Per CDM: it appears the temperature appears rather high. Please reconcile' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 01:06:14
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered '97.4' C	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'Moderate (Moderate)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'Moderate (Moderate)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:23:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:48:49

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:51
User entered 'Day 2 (Day 2)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered '22 Sep 2020'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered '0'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered '94'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User entered '%'	System	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered '36.4' C	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:23:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:56:40

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:51
User entered 'Day 3 (Day 3)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered '23 Sep 2020'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered '0'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered '93'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User entered '%'	System	24 Sep 2020 16:17:30

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered '37.1' C	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:23:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:17:30

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:51
User entered 'Day 4 (Day 4)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered '24 Sep 2020'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered '0'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered '96'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User entered '%'	System	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered '36.3' C	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'Not Done (Not Done)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:23:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:46:31
User entered 'None (None)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:30:02

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	23 Oct 2020 17:08:51
User entered 'Day 2 (Day 2)'	Cynthia Kunakom (b) (4) (b) (4)	23 Oct 2020 17:06:46

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered '20 Sep 2020'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered 'I'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User entered empty.	System	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:23:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:46

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:51
User entered 'Day 1 (Day 1)'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered '19 Sep 2020'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered 'I'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User entered empty.	System	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:23:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:06:59

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:51
User entered empty.	(b) (4)	
	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07
	(b) (4)	

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered '18 Sep 2020'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered 'I'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User entered empty.	System	23 Oct 2020 17:07:07

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:23:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:07

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Day 7 (Day 7)' reason for change:	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:51
Data Entry Error	(b) (4)	
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered '17 Sep 2020'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered 'I'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User entered empty.	System	23 Oct 2020 17:07:15

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

US3162003

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Form: Symptom Log (8)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:23:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:15

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:51
User entered empty.	(b) (4)	
	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23
	(b) (4)	

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered '16 Sep 2020'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered 'I'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User entered empty.	System	23 Oct 2020 17:07:23

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:23:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:23

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:51
User entered empty.	(b) (4)	
	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32
	(b) (4)	

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered '15 Sep 2020'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered 'I'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User entered empty.	System	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:23:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:32

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:51
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered '14 Sep 2020'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered 'I'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User entered empty.	System	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:23:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:43

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Day 3 (Day 3)' reason for change:	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:51
Data Entry Error	(b) (4)	
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52
	(b) (4)	

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered '13 Sep 2020'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered 'I'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User entered empty.	System	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:23:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:07:52

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Day 2 (Day 2)'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered '12 Sep 2020'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered 'I'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User entered empty.	System	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:23:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:03

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Day 1 (Day 1)'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered '11 Sep 2020'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered 'I'	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User entered empty.	System	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

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Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:23:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:14:24
User entered empty.	Cynthia Kunakom (b) (4)	23 Oct 2020 17:08:14

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:23:27

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:49:59
User entered '21 Sep 2020'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:49:44

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:23:27

[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 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:49:59
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:49:44

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:23:27

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 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User closed query 'Please provide the negative COVID-19 test result, not found in eSource. Thank you.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 23:25:31
Query 'Please provide the negative COVID-19 test result, not found in eSource. Thank you.' answered with 'It is now attached to Illness visit 1 in the source, which is on page 5' (Site from CRA).	Judith Kirstein (b) (4)	29 Sep 2020 23:55:27
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:49:59
User opened query 'Please provide the negative COVID-19 test result, not found in eSource. Thank you.' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 22:49:48
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 05:12:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 05:12:06
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	25 Sep 2020 05:12:06
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 14:49:44
User entered empty.	Cynthia Kunakom (b) (4)	23 Sep 2020 14:49:44

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:23:27

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:49:59
User entered '21 Sep 2020'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:49:44

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:23:27

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:49:59
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:49:44

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:23:27

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:49:59
User entered empty.	Cynthia Kunakom (b) (4)	23 Sep 2020 14:49:44

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:23:27

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:49:59
User entered 'No (N)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:49:44

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:23:27

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:49:59
User entered empty.	Cynthia Kunakom (b) (4)	23 Sep 2020 14:49:44

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:23:27

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:49:59
User entered empty.	Cynthia Kunakom (b) (4)	23 Sep 2020 14:49:44

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:23:27

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User entered '0'	System	25 Sep 2020 05:12:06

US3162003

Folder: Covid-19 Assessment 21 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:23:27

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:49
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:27:53
User entered 'No (N)'	Cynthia Kunakom (b) (4)	08 Oct 2020 15:50:34

US3162003

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:23:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User accepted default value 'Day 3 (Day 3)'	Cynthia Kunakom (b) (4) (b) (4)	24 Sep 2020 16:15:13

US3162003

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:23:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:59:46
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:13

US3162003

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:23:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:59:46
User entered '23 Sep 2020'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:13

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:23:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User accepted default value 'Day 5 (Day 5)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:13
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:23:27

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:05:15
User closed query 'It appears subject tested negative for covid, which is why the saliva samples were not collected day 5 and beyond. If confirmed, then please update this "No" to "NA (Covid-19 Negative)" for this and all subsequent saliva sample days. Thank you!' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:05:13
Query 'It appears subject tested negative for covid, which is why the saliva samples were not collected day 5 and beyond. If confirmed, then please update this "No" to "NA (Covid-19 Negative)" for this and all subsequent saliva sample days. Thank you!' answered with 'Updated' (Site from CRA).	Judith Kirstein (b) (4)	26 Oct 2020 19:52:53
DataPoint Un-verified.	Judith Kirstein (b) (4)	26 Oct 2020 19:52:43
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	26 Oct 2020 19:52:43
User opened query 'It appears subject tested negative for covid, which is why the saliva samples were not collected day 5 and beyond. If confirmed, then please update this "No" to "NA (Covid-19 Negative)" for this and all subsequent saliva sample days. Thank you!' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 19:35:11
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:59:46
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 05:12:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 05:12:43
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	25 Sep 2020 05:12:43
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 16:15:13

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:23:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	24 Sep 2020 16:15:13

US3162003

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:23:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:59:46
User entered empty.	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:13

US3162003

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:23:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User accepted default value 'Day 7 (Day 7)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:13
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:23:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:05:15
DataPoint Un-verified.	Judith Kirstein (b) (4)	26 Oct 2020 19:53:08
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	26 Oct 2020 19:53:08
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:59:46
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 05:12:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 05:12:43
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	25 Sep 2020 05:12:43
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 16:15:13
User entered empty.	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:13

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:23:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:59:46
User entered empty.	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:13

US3162003

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:23:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User accepted default value 'Day 9 (Day 9)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:13
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:23:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:05:15
DataPoint Un-verified.	Judith Kirstein (b) (4)	26 Oct 2020 19:53:15
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	26 Oct 2020 19:53:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:59:46
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 05:12:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 05:12:43
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	25 Sep 2020 05:12:43
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 16:15:13
User entered empty.	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:13

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:23:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:59:46
User entered empty.	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:13

US3162003

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:23:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User accepted default value 'Day 14 (Day 14)'	Cynthia Kunakom (b) (4) (b) (4)	24 Sep 2020 16:15:13

US3162003

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:23:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:05:15
DataPoint Un-verified.	Judith Kirstein (b) (4)	26 Oct 2020 19:53:21
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	26 Oct 2020 19:53:21
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:59:46
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 05:12:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 05:12:43
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	25 Sep 2020 05:12:43
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 16:15:13
User entered empty.	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:13

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:23:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:59:46
User entered empty.	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:13

US3162003

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:23:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User accepted default value 'Day 21 (Day 21)'	Cynthia Kunakom (b) (4) (b) (4)	24 Sep 2020 16:15:13

US3162003

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:23:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:05:15
DataPoint Un-verified.	Judith Kirstein (b) (4)	26 Oct 2020 19:53:29
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	26 Oct 2020 19:53:29
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:59:46
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 05:12:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 05:12:43
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	25 Sep 2020 05:12:43
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 16:15:13
User entered empty.	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:13

US3162003

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:23:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:59:46
User entered empty.	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:13

US3162003

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:23:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User accepted default value 'Day 28 (Day 28)'	Cynthia Kunakom (b) (4) (b) (4)	24 Sep 2020 16:15:13

US3162003

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:23:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:05:15
DataPoint Un-verified.	Judith Kirstein (b) (4)	26 Oct 2020 19:53:35
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	26 Oct 2020 19:53:35
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:59:46
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 05:12:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 05:12:43
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	25 Sep 2020 05:12:43
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 16:15:13
User entered empty.	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:13

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:23:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:59:46
User entered empty.	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:13

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:27:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:43

US3162003

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:27:18
User entered '21 Sep 2020' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	25 Sep 2020 14:21:19
User entered '23 Sep 2020'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:43

US3162003

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:27:18
User entered 'Clinic (Clinic)'	Cynthia Kunakom (b) (4)	24 Sep 2020 16:15:43

US3162003

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User entered 'SICKD1'	System	24 Sep 2020 16:15:43

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:36:58
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:20:31

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:36:58
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	25 Sep 2020 14:21:19
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	25 Sep 2020 14:21:19
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	25 Sep 2020 14:20:31
User entered '21 Sep 2020'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:20:31

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:36:58
User entered '11:23'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:20:31

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User entered '21 Sep 2020 11:23'	System	25 Sep 2020 14:20:31

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:36:58
User entered '157.5' cm	Cynthia Kunakom (b) (4)	25 Sep 2020 14:20:31
DataPoint set to visible.	(b) (4) System	24 Sep 2020 16:15:43

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:36:58
User entered '73.6' kg	Cynthia Kunakom (b) (4)	25 Sep 2020 14:20:31
DataPoint set to visible.	System	24 Sep 2020 16:15:43

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:36:58
User entered '97.4' F	Cynthia Kunakom (b) (4)	25 Sep 2020 14:20:31

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:36:58
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:20:31

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:36:58
User entered empty.	Cynthia Kunakom (b) (4)	25 Sep 2020 14:20:31

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:36:58
User entered '66'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:20:31

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User entered 'bpm'	System	25 Sep 2020 14:20:31

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:36:58
User entered '16'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:20:31

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User entered 'breaths/min'	System	25 Sep 2020 14:20:31

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:36:58
User entered '137'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:20:31

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User entered 'mmHg'	System	25 Sep 2020 14:20:31

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:36:58
User entered '69'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:20:31

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User entered 'mmHg'	System	25 Sep 2020 14:20:31

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13

US3162003

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13

US3162003

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:27

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:37:07
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:21:53

US3162003

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:37:07
User entered '21 Sep 2020'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:21:53

US3162003

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:23:27

[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 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:37:19
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:22:05

US3162003

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:23:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:13
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 22:37:21
User entered '21 Sep 2020'	Cynthia Kunakom (b) (4)	25 Sep 2020 14:22:05

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:53:59
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 22JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded on the Immunogenicity Assessment form within this folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 06:41:29
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 22JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded on the Immunogenicity Assessment form within this folder. Please clarify and update as appropriate.' answered with 'Form has been completed now' (Site from DM).	Judith Kirstein (b) (4)	17 Feb 2021 01:29:31
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 22JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded on the Immunogenicity Assessment form within this folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 18:25:09
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	27 Jan 2021 23:15:53

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:53:59
User entered '22 Jan 2021'	Tiffany Williams (b) (4)	27 Jan 2021 23:15:53

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:53:59
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4)	27 Jan 2021 23:15:53

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 23:15:53

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:23:27

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:34:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered '22 Jan 2021'	Tiffany Williams (b) (4)	27 Jan 2021 23:16:34

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:23:27

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:47:17
User entered '0'	Judith Kirstein (b) (4)	09 Mar 2021 20:51:06
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:01:30

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:23:27

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:34:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	27 Jan 2021 23:16:34

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:23:27

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:47:20
User entered 'Amendment 6 or later (Amendment 6 or later)'	Judith Kirstein (b) (4)	09 Mar 2021 20:51:06
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:01:30

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:23:27

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:34:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered '22 Jan 2021'	Tiffany Williams (b) (4)	27 Jan 2021 23:16:34

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:23:27

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:34:12
Signature has been broken.	Judith Kirstein (b) (4)	17 Feb 2021 01:12:45
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	17 Feb 2021 01:12:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4)	27 Jan 2021 23:16:34

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:23:27

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:34:12
Signature has been broken.	Judith Kirstein (b) (4)	17 Feb 2021 01:12:45
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	17 Feb 2021 01:12:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4)	27 Jan 2021 23:16:34

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:23:27

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:34:12
Signature has been broken.	Judith Kirstein (b) (4)	17 Feb 2021 01:12:45
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	17 Feb 2021 01:12:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4)	27 Jan 2021 23:16:34

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:23:27

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:34:12
Signature has been broken.	Judith Kirstein (b) (4)	17 Feb 2021 01:12:45
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	17 Feb 2021 01:12:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	27 Jan 2021 23:16:34

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:23:27

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User entered empty.	System	17 Feb 2021 01:12:45
User entered 'I'	System	27 Jan 2021 23:16:34

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:23:27

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User entered empty.	System	17 Feb 2021 01:12:45
User entered 'I'	System	27 Jan 2021 23:16:34

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:34:57
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	17 Feb 2021 01:28:11

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:34:57
User entered '22 Jan 2021'	Judith Kirstein (b) (4)	17 Feb 2021 01:28:11

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:34:57
User entered '09:27'	Judith Kirstein (b) (4)	17 Feb 2021 01:28:11

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User entered '22 Jan 2021 09:27'	System	17 Feb 2021 01:28:11

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:23:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:01
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	17 Feb 2021 01:28:43

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:23:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:01
User entered '22 Jan 2021'	Judith Kirstein (b) (4)	17 Feb 2021 01:28:43

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:23:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:01
User entered '09:29'	Judith Kirstein (b) (4)	17 Feb 2021 01:28:43

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:23:27

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User entered '22 Jan 2021 09:29'	System	17 Feb 2021 01:28:43

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:05
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	27 Jan 2021 23:17:11

US3162003

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:07
User entered 'I'	System	27 Jan 2021 23:17:11

US3162003

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:23:27

[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 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:22:20
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:01:43
User entered 'Yes (Y)' reason for change: New Information	Cynthia Kunakom (b) (4)	03 Sep 2020 19:01:43
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:44:43
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:23:46

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 14:10:09

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User coded data point as SOC: Hepatobiliary disorders, HLG: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis acute, LLT: Acute cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:04:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:04:42
Data point term sent to Coder	System	03 Sep 2020 19:03:58
User entered 'Acute cholecystitis'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'No (N)'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'No (N)'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '27 Aug 2020'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User entered empty.	System	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'No (N)'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '27 Aug 2020'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User entered empty.	System	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Grade 4 (Grade 4)'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4), (b) (6)	04 Sep 2020 02:20:40
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'Confirm correct.' (Site from System).	Cynthia Kunakom (b) (4)	03 Sep 2020 19:03:11
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	03 Sep 2020 19:02:59
User entered 'No (N)'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'None (NONE)'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '1'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[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 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User entered '0'	System	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:09
User entered 'I'	System	03 Sep 2020 19:02:59

US3162003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:23:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 14:10:09

US3162003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:27

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:24:52
User entered	System	11 Sep 2020 00:24:27
'USA-US074-2020-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	11 Sep 2020 00:24:27

US3162003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:27

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	16 Sep 2020 00:27:20
DataPoint Verified.	Coder Import (b) (4)	09 Sep 2020 16:31:52
User coded data point as SOC: Cardiac disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Acute myocardial infarction - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 16:31:52
Data point term sent to Coder	(b) (4)	
User entered 'Acute Myocardial Infarction' reason for change: New Information	System	09 Sep 2020 16:30:28
	Judith Kirstein (b) (4)	09 Sep 2020 16:30:24
	(b) (4)	
Data point term sent to Coder	System	08 Sep 2020 19:19:45
User entered 'Anterior chest wall pain'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Yes (Y)' reason for change: New Information	Judith Kirstein (b) (4)	09 Sep 2020 16:30:24
User entered 'No (N)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'No (N)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'No (N)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '07 Sep 2020'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User closed query 'Per CDM: Response noted. As per CCGs pages 31-32, Start time is not required, unless start time is within 24 hours of dosing time. Please update the data accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 18:07:30
Query 'Per CDM: Response noted. As per CCGs pages 31-32, Start time is not required, unless start time is within 24 hours of dosing time. Please update the data accordingly. Thank you.' answered with 'Updated.' (Site from DM).	Cynthia Kunakom (b) (4)	11 Sep 2020 20:12:43
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4)	11 Sep 2020 20:12:28
	(b) (4)	
User opened query 'Per CDM: Response noted. As per CCGs pages 31-32, Start time is not required, unless start time is within 24 hours of dosing time. Please update the data accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 12:18:12
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).	(b) (4), (b) (6)	11 Sep 2020 12:13:13
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Start time known and entered' (Site from System).	Judith Kirstein (b) (4)	09 Sep 2020 16:31:27
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	09 Sep 2020 16:30:24
User entered '12:30' reason for change: New Information	Judith Kirstein (b) (4)	09 Sep 2020 16:30:24
User entered empty.	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 20:12:28
User entered '07 Sep 2020 12:30'	System	09 Sep 2020 16:30:24
User entered empty.	System	08 Sep 2020 19:19:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'No (N)' reason for change: New Information	Cynthia Kunakom (b) (4)	11 Sep 2020 20:12:28
	(b) (4)	
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '08 Sep 2020' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	11 Sep 2020 20:12:28
	(b) (4)	
User entered empty.	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:27

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:19:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:27

Severity

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User closed query 'PV Query: The event intensity is "Grade 4" for this event of acute myocardial infarction. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.' (Site from Safety). Query 'PV Query: The event intensity is "Grade 4" for this event of acute myocardial infarction. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.' answered with 'Life threatening added per query' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:37:47
User opened query 'PV Query: The event intensity is "Grade 4" for this event of acute myocardial infarction. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.' (Site from Safety).	Judith Kirstein (b) (4)	16 Sep 2020 19:57:14
User opened query 'PV Query: The event intensity is "Grade 4" for this event of acute myocardial infarction. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 18:59:01
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Grade 4 (Grade 4)' reason for change: New Information	Judith Kirstein (b) (4)	09 Sep 2020 16:30:24
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	16 Sep 2020 00:27:20
DataPoint Verified.	Judith Kirstein (b) (4)	09 Sep 2020 16:30:24
User entered 'Yes (Y)' reason for change: New Information	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
User entered 'No (N)'	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
DataPoint Un-verified.	Judith Kirstein (b) (4)	16 Sep 2020 19:56:47
User entered '1' reason for change: Data Entry Error	Judith Kirstein (b) (4)	16 Sep 2020 19:56:47
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:27

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	23 Sep 2020 16:30:20
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:30:12
User closed query 'PV Query:: Please provide the hospital discharge summary when available.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:30:06
User closed query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).	Cynthia Kunakom (b) (4)	22 Sep 2020 17:11:28
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Not tested.' (Site from Safety).	Cynthia Kunakom (b) (4)	22 Sep 2020 17:11:04
Query 'PV Query:: Please provide the hospital discharge summary when available.' answered with 'Updated.' (Site from Safety).	Judith Kirstein (b) (4)	22 Sep 2020 02:03:47
Query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' answered with 'Subject was in cardiac care unit from 9Sep20 to 10Sep20' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 18:59:26
User opened query 'PV Query:: Please provide the hospital discharge summary when available.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 18:59:11
User opened query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 18:58:11
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 00:27:20
DataPoint Verified.		

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 02:21:56
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'See below' (Site from System).	Judith Kirstein (b) (4)	09 Sep 2020 16:32:20
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Sep 2020 16:30:24
User entered '1' reason for change: New Information	Judith Kirstein (b) (4)	09 Sep 2020 16:30:24
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	08 Sep 2020 19:19:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:27

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
User closed query 'PV Query: Please confirm hospital admission date of 08 Sep 2020 since this is also the event end date.' (Site from Safety).		17 Sep 2020 12:38:25
Query 'PV Query: Please confirm hospital admission date of 08 Sep 2020 since this is also the event end date.' answered with 'The event began 07Sep20 and was a completed infarct as of 08Sep20' (Site from Safety).	Judith Kirstein (b) (4)	16 Sep 2020 19:58:10
User opened query 'PV Query: Please confirm hospital admission date of 08 Sep 2020 since this is also the event end date.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 18:58:35
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '8 Sep 2020' reason for change: New Information	Judith Kirstein (b) (4)	09 Sep 2020 16:30:24
User entered empty.	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:38:28
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Discharged 10Sep20' (Site from Safety).	Judith Kirstein (b) (4)	16 Sep 2020 20:04:00
DataPoint Un-verified.	Judith Kirstein (b) (4)	16 Sep 2020 19:58:36
User entered '10 Sep 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	16 Sep 2020 19:58:36
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 18:58:21
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Yes (Y)' reason for change: New Information	Judith Kirstein (b) (4)	09 Sep 2020 16:30:24
User entered empty.	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 02:28:38
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'Unknown at this time' (Site from System).	Judith Kirstein (b) (4)	09 Sep 2020 16:32:10
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	09 Sep 2020 16:30:24
User entered empty.	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:04:39
User closed query 'PV Query: As the subject had received both doses of study drug prior to event onset, please update action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 12:56:33
Query 'PV Query: As the subject had received both doses of study drug prior to event onset, please update action taken from none to not applicable.' answered with 'Changed per query' (Site from Safety).	Judith Kirstein (b) (4)	14 Oct 2020 18:59:35
DataPoint Un-verified.	Judith Kirstein (b) (4)	14 Oct 2020 18:59:20
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	14 Oct 2020 18:59:20
User opened query 'PV Query: As the subject had received both doses of study drug prior to event onset, please update action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 17:10:44
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'None (NONE)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:23:27

None

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	23 Sep 2020 16:30:31
User closed query 'PV Query: Please report any treatment provided for the event of acute myocardial infarction.' (Site from Safety).	Judith Kirstein (b) (4)	22 Sep 2020 02:07:47
Query 'PV Query: Please report any treatment provided for the event of acute myocardial infarction.' answered with 'Subject on 8Sep20 received morphine sulfate 2 mg IV one time for pain, Nitroglycerin 0.4 mg sublingual once, Aspirin 325 mg once, ondansetron 4 mg IV one time for nausea, and Heparin 4000 IU as a loading dose, then a heparin drip at 8.7 ml per hour (solution contained 25,000 IU heparin in 250 cc D5W. This was all given in the ER at San Geronio Hospital before subject was transferred to Riverside Community Hospital. We should receive those records soon.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 18:59:45
User opened query 'PV Query: Please report any treatment provided for the event of acute myocardial infarction.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 00:27:20
DataPoint Verified.	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
User entered '0'	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'I'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '1' reason for change: New Information	Judith Kirstein (b) (4)	09 Sep 2020 16:30:24
User entered '0'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	11 Sep 2020 20:12:28
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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[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 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
User closed query 'PV Query: Please consider adding 'previous smoker' to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 16:13:03
Query 'PV Query: Please consider adding 'previous smoker' to MH eCRF.' answered with 'Added per query' (Site from Safety).	Judith Kirstein (b) (4)	05 Oct 2020 19:50:43
User opened query 'PV Query: Please consider adding 'previous smoker' to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:27:25
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 13:32:59
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 13:32:56
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 13:31:59
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 13:31:48
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:30:36

US3162003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:27

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'On 8Sep20: CK 376 (49-397 U/L), CK-MB 27.9 (0.5-3.6 ng/ml), Troponin 12.60 (0.01-0.50 ng/mL), BNP 3605 (0-1800 pg/mL). ECG's at 1720 and 1859 showed Deep inverted T waves in 2,3 and avF and was read as non-STEMI . Chest xray showed cardiomegaly and slight vascular congestion. This was all done in the ER of San Gorgonio Hospital before she was transferred to Riverside Community Hospital. Awaiting those records.' (Site from Safety).	Judith Kirstein (b) (4)	22 Sep 2020 02:16:04
User closed query 'PV Query:: Please report if the patient had any known risk factors for myocardial infarction (ie. family history, smoking, hypertension, etc.).' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:38:44
Query 'PV Query:: Please report if the patient had any known risk factors for myocardial infarction (ie. family history, smoking, hypertension, etc.).' answered with 'Smoked 1/2 pack per day for 68 years, stopped smoking in 2019. Has hyperlipidemia but no hypertension,' (Site from Safety).	Judith Kirstein (b) (4)	16 Sep 2020 20:03:19
User opened query 'PV Query:: Please report if the patient had any known risk factors for myocardial infarction (ie. family history, smoking, hypertension, etc.).' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 18:59:54
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 18:58:44
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Subject had onset of anterior chest pain on 07Sep. Went to ER 08Sep evening, diagnosed with myocardial infarction, admitted.' reason for change: New Information	Judith Kirstein (b) (4)	09 Sep 2020 16:30:24
User entered empty.	Cynthia Kunakom (b) (4)	08 Sep 2020 19:19:32

US3162003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 16:30:24
User entered '0'	System	08 Sep 2020 19:19:32

US3162003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 16:30:24
User entered '0'	System	08 Sep 2020 19:19:32

US3162003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Sep 2020 16:30:24

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 20:16:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 20:16:47
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 20:15:09
User entered 'Coronary artery disease'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'No (N)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'No (N)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
Query 'Please verify the start time noted in source as 09:30. Thank you.' canceled (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 00:26:19
User opened query 'Please verify the start time noted in source as 09:30. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 00:26:12
User entered '09 Sep 2020'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	31 Oct 2020 01:00:33
User closed query 'Please verify the start time noted in source as 09:30. Thank you. ' (Site from CRA).	Judith Kirstein (b) (4)	17 Sep 2020 20:04:24
Query 'Please verify the start time noted in source as 09:30. Thank you. ' answered with 'time the subject had angiogram and the coronary artery disease was discovered' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 00:27:20
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:26:28
User opened query 'Please verify the start time noted in source as 09:30. Thank you. ' (Site from CRA).	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
User entered empty.	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 20:15:06

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 20:15:06

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	11 Sep 2020 20:44:52
User entered 'Grade 4 (Grade 4)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	11 Sep 2020 20:44:52
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	11 Sep 2020 20:44:52
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	11 Sep 2020 20:15:06
User entered 'No (N)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'None (NONE)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered '0'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'I'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered 'I'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 20:15:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 20:15:30
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:30
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 20:15:06
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[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 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:27:20
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:15:06
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Sep 2020 20:15:06

US3162003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 20:15:06

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 14:10:26

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:53:36
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 11:46:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 11:46:43
Data point term sent to Coder	System	22 Sep 2020 03:02:53
User entered 'Nausea due to acute myocardial infarction'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:53:38
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:53:40
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:53:42
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:53:46
User entered '8 Sep 2020'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:53:48
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User entered empty.	System	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:53:50
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:53:52
User entered '8 Sep 2020'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:53:56
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User entered empty.	System	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:53:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:53:59
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:01
User entered '0'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:03
User entered '0'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:05
User entered '0'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:06
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:09
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:11
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:13
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:15
User entered '0'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:17
User entered '0'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:18
User entered '0'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:20
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:23
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:24
User entered 'None (NONE)'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:26
User entered '0'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:28
User entered 'I'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:29
User entered '0'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

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 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:33
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:54:36
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User entered '0'	System	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:26
User entered 'I'	System	22 Sep 2020 03:02:33

US3162003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 14:10:26

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 14:10:20

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 10:20:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 10:20:06
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 19:00:35
User closed query 'Please verify with the PI if the event should be updated to Shortness of Breath, secondary to Carvedilol. See Progress notes dated 21-22 Sep 2020. Thank you' (Site from CRA).	(b) (4), (b) (6)	02 Oct 2020 19:00:29
Data point term sent to Coder	System	29 Sep 2020 22:51:46
Query 'Please verify with the PI if the event should be updated to Shortness of Breath, secondary to Carvedilol. See Progress notes dated 21-22 Sep 2020. Thank you' answered with 'UPDATED PER QUERY' (Site from CRA).	Judith Kirstein (b) (4)	29 Sep 2020 22:51:02
DataPoint Un-verified.	Judith Kirstein (b) (4)	29 Sep 2020 22:50:50
Coding entries removed.	Judith Kirstein (b) (4)	29 Sep 2020 22:50:50
User entered 'SHORTNESS OF BREATH SECONDARY TO CARVEDILOL' reason for change: Data Entry Error	Judith Kirstein (b) (4)	29 Sep 2020 22:50:50
User opened query 'Please verify with the PI if the event should be updated to Shortness of Breath, secondary to Carvedilol. See Progress notes dated 21-22 Sep 2020. Thank you' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 20:50:33
Query 'Please verify with the PI if the event should be updated to Shortness of Breath, secondary to Carvedilol. See Progress notes dated 21 Sep 2020. Thank you.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 20:50:23

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Please verify with the PI if the event should be updated to Shortness of Breath, secondary to Carvedilol. See Progress notes dated 21 Sep 2020. Thank you.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:49:42
	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 14:53:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 14:53:37
	(b) (4)	
Data point term sent to Coder	System	23 Sep 2020 14:53:05
User entered 'Shortness of breath'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58
	(b) (4)	

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered 'No (N)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 15:24:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 15:24:14
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Sep 2020 15:24:14
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 14:52:58
User entered empty.	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
Query 'Source documents note the start date as 09 Sep 2020, please verify. Thank you.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 19:56:16
User opened query 'Source documents note the start date as 09 Sep 2020, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 19:55:31
User entered '11 Sep 2020'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
Query 'Source documents note the start time as 0930, please verify. Thank you.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 19:56:17
User opened query 'Source documents note the start time as 0930, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 19:56:02
User entered empty.	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User entered empty.	System	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered 'No (N)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered '22 Sep 2020'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered empty.	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User entered empty.	System	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered 'No (N)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered '0'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered '0'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered '0'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered empty.	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered empty.	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered empty.	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered empty.	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered '0'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered '0'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered '0'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered 'None (NONE)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered 'I'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered '0'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered '0'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[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 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered empty.	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:57:20
User entered empty.	Cynthia Kunakom (b) (4)	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User entered '0'	System	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:20
User entered 'I'	System	23 Sep 2020 14:52:58

US3162003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:23:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 14:10:20

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 03:00:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 03:00:28
Data point term sent to Coder	System	23 Mar 2021 02:59:55
User entered 'bilateral lower extremity edema'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'No (N)'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'No (N)'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	23 Mar 2021 02:59:30
User entered '15 Dec 2020' reason for change: Data Entry Error	Jessica Fisher (b) (4)	23 Mar 2021 02:59:30
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	23 Mar 2021 02:59:22
User entered '15 Dec 2021'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 05:21:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'Ongoing' (Site from DM).	Judith Kirstein (b) (4)	31 Mar 2021 04:01:33
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 01:56:25
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'No (N)'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'I'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:23
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:23:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 02:59:22

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User coded data point as SOC: Hepatobiliary disorders, HLGT: Bile duct disorders, HLT: Bile duct infections and inflammations, PT: Biliary colic, LLT: Biliary colic - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 14:43:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 14:43:37
Data point term sent to Coder	System	23 Mar 2021 03:00:55
User entered 'intermittent biliary colic'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'No (N)'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'No (N)'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '01 Sep 2020'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'No (N)'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'I'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:55:28
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:43
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 03:00:13

US3162003

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:23:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 03:00:13

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:23:27

[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 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:44:55
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:08:41

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 04:11:14
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 04:11:14
	(b) (4)	
Data point term sent to Coder	System	05 Aug 2020 04:10:12
User entered 'trelegy ellipta'	Jared Bradshaw (b) (4)	05 Aug 2020 04:09:39
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 05:24:47
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 05:24:26
	(b) (4)	
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:09:39
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'chronic obstructive pulmonary disease'	Jared Bradshaw (b) (4)	05 Aug 2020 04:09:39
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '1'	Jared Bradshaw (b) (4)	05 Aug 2020 04:09:39
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'puff (PUFF)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:09:39
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:09:39
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'once daily (QD)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:09:39
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:09:39
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jared Bradshaw (b) (4)	05 Aug 2020 04:09:39
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:09:39
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	05 Aug 2020 17:36:53
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Jared Bradshaw (b) (4)	05 Aug 2020 04:24:23
answered with 'Per the CRF, all con meds must be entered. Please fix EDC' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 04:09:39
User entered 'un UNK 2019'	Jared Bradshaw (b) (4)	05 Aug 2020 04:09:39
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '0'	Jared Bradshaw (b) (4)	05 Aug 2020 04:09:39
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:09:39
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:09:39
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:09:39
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 04:09:39

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 04:09:39

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 04:09:39

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 04:12:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	05 Aug 2020 04:12:15
Data point term sent to Coder	System	05 Aug 2020 04:11:12
User entered 'atorvastatin'	Jared Bradshaw (b) (4)	05 Aug 2020 04:10:27
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:10:27

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'hyperlipidemia'	Jared Bradshaw (b) (4)	05 Aug 2020 04:10:27

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '10'	Jared Bradshaw (b) (4)	05 Aug 2020 04:10:27

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:10:27

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:10:27

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'once daily (QD)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:10:27

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:10:27

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:10:27

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:10:27

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	05 Aug 2020 17:38:56
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.'	Jared Bradshaw (b) (4)	05 Aug 2020 04:24:32
answered with 'Per the CRF, all con meds must be entered. Please fix EDC' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 04:10:27
User entered 'un UNK 2005'	Jared Bradshaw (b) (4)	05 Aug 2020 04:10:27
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '0'	Jared Bradshaw (b) (4)	05 Aug 2020 04:10:27

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:16:27
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Cynthia Kunakom (b) (4)	11 Sep 2020 20:16:27
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:10:27
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:16:27
User entered '08 Sep 2020' reason for change: New Information	(b) (4)	
DataPoint Verified.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:16:27
	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:10:27
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:10:27

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User entered '1'	System	05 Aug 2020 04:10:27

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User entered '1'	System	05 Aug 2020 04:10:27

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:27
User entered '804 (804)'	System	05 Aug 2020 04:10:27

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 17:38:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 17:38:58
Data point term sent to Coder	System	05 Aug 2020 04:12:13
User entered 'tramadol'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:11:22

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:11:22
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
	(b) (4)	
User entered 'cervical disc disease'	Jared Bradshaw (b) (4)	05 Aug 2020 04:11:22
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '50'	Jared Bradshaw (b) (4)	05 Aug 2020 04:11:22
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:11:22
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:11:22
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'once daily (QD)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:11:22
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:11:22
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:11:22
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:11:22
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '10 Jul 2020'	Jared Bradshaw (b) (4)	05 Aug 2020 04:11:22
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '0'	Jared Bradshaw (b) (4)	05 Aug 2020 04:11:22
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:11:22
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:11:22
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:11:22
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 04:11:22

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 04:11:22

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 04:11:22

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 22:57:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 22:57:58
Data point term sent to Coder	System	05 Aug 2020 04:12:13
User entered 'glucosamine/chondroitin'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:12:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 05:24:59
	(b) (4)	
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:11
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
	(b) (4)	
User entered 'cervical disc disease'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:11
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'I'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:11
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'tablet (TABLET)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:11
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:11
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'twice daily (BID)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:11
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:11
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:11
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:11
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		05 Aug 2020 17:39:41
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.'	Jared Bradshaw (b) (4)	05 Aug 2020 04:24:43
answered with 'Per the CRF, all con meds must be entered. Please fix EDC' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 04:12:11
User entered 'un UNK 2010'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:11
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '0'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:11
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:11
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:11
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:11
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Aug 2020 04:12:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 04:12:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 04:12:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, PRODUCT: OMEGA-3 NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 04:14:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 04:14:02
Data point term sent to Coder	System	05 Aug 2020 04:13:13
User entered 'Omega 3'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:51

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 05:25:06
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:51

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'health maintenance'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:51

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '1000'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:51

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:51

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:51

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'once daily (QD)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:51

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:51

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:51

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:51

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	05 Aug 2020 17:39:52
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.'	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:04
answered with 'Per the CRF, all con meds must be entered. Please fix EDC' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 04:12:51
User entered 'un UNK 2010'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:51
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
Query 'A Stop date is noted in the source. Please verify. Thank you.' canceled (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 19:55:19
User opened query 'A Stop date is noted in the source. Please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 19:55:00
User entered '0'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:51
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User closed query 'Source document notes the stop date as UN/UN/2020, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 16:00:36
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
Query 'Source document notes the stop date as UN/UN/2020, please verify. Thank you.' answered with 'agreed, updated.' (Site from CRA).	Cynthia Kunakom (b) (4)	03 Sep 2020 19:01:08
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:01:02
User entered 'No (N)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	03 Sep 2020 19:01:02
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User opened query 'Source document notes the stop date as UN/UN/2020, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 19:54:32
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:51

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User closed query 'Source document notes the stop date as UN/UN/2020, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 16:00:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
Query 'Source document notes the stop date as UN/UN/2020, please verify. Thank you.' answered with 'agreed, updated.' (Site from CRA).	Cynthia Kunakom (b) (4)	03 Sep 2020 19:01:10
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:01:02
User entered 'un UNK 2020' reason for change:	Cynthia Kunakom (b) (4)	03 Sep 2020 19:01:02
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User opened query 'Source document notes the stop date as UN/UN/2020, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 19:55:51
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:51

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:12:51

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User entered '1'	System	05 Aug 2020 04:12:51

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User entered '1'	System	05 Aug 2020 04:12:51

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:25:39
User entered '804 (804)'	System	05 Aug 2020 04:12:51

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN E NOS, PRODUCTSYNONYM: VITAMIN E [VITAMIN E NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 04:15:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 04:15:03
	(b) (4)	
Data point term sent to Coder	System	05 Aug 2020 04:14:13
User entered 'vitamin e'	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:38
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 05:25:12
	(b) (4)	
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:38
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'health maintenance'	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:38
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '400'	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:38
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'IU (IU)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:38
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:38
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'once daily (QD)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:38
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:38
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:38
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:38
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	05 Aug 2020 17:39:59
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.'	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:46
answered with 'Per the CRF, all con meds must be entered. Please fix EDC' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 04:13:38
User entered 'un UNK 2010'	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:38
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '0'	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:38
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:38
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:38
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:13:38
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 04:13:38

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 04:13:38

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 04:13:38

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 04:16:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 04:16:06
Data point term sent to Coder	System	05 Aug 2020 04:15:15
User entered 'multivitamin'	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 05:25:20
	(b) (4)	
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'health maintenance'	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '1'	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'tablet (TABLET)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'once daily (QD)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		05 Aug 2020 17:40:14
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.'	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:31
answered with 'Per the CRF, all con meds must be entered. Please fix EDC' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 04:14:23
User entered 'un UNK 2000'	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '0'	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 04:14:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 04:14:36
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:36
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 04:14:23
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:14:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 04:14:23

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 04:14:23

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 04:14:23

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
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)	05 Aug 2020 04:16:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 04:16:06
	(b) (4)	
Data point term sent to Coder	System	05 Aug 2020 04:15:14
User entered 'aspirin'	Jared Bradshaw (b) (4)	05 Aug 2020 04:15:12
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	06 Aug 2020 02:01:57
	(b) (4)	
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:15:12
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'health maintenance'	Jared Bradshaw (b) (4)	05 Aug 2020 04:15:12
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '81'	Jared Bradshaw (b) (4)	05 Aug 2020 04:15:12
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:15:12
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:15:12
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'once daily (QD)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:15:12
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:15:12
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:15:12
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:15:12
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		05 Aug 2020 17:40:25
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.'	Jared Bradshaw (b) (4)	05 Aug 2020 04:15:21
answered with 'Per the CRF, all con meds must be entered. Please fix EDC' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 04:15:12
User entered 'un UNK 2005'	Jared Bradshaw (b) (4)	05 Aug 2020 04:15:12
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '0'	Jared Bradshaw (b) (4)	05 Aug 2020 04:15:12
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:15:12
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:15:12
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:15:12
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 04:15:12

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 04:15:12

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 04:15:12

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User closed query 'Progress notes on 07Sep2020 document the subject took Baclofen for chest pain. Please verify and update EDC if appropriate (AE and Con Meds). Thank you.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 23:16:52
Query 'Progress notes on 07Sep2020 document the subject took Baclofen for chest pain. Please verify and update EDC if appropriate (AE and Con Meds). Thank you.' answered with 'Per phone call with subject on 29Sep20, she did not take baclofen, took tramadol for the chest pain. Con med list updated.' (Site from CRA).	Judith Kirstein (b) (4)	30 Sep 2020 00:13:41
User opened query 'Progress notes on 07Sep2020 document the subject took Baclofen for chest pain. Please verify and update EDC if appropriate (AE and Con Meds). Thank you.' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 20:18:22
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Aug 2020 17:46:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Aug 2020 17:46:59
Data point term sent to Coder	System	05 Aug 2020 04:17:17
User entered 'albuterol sulfate for nebulizer .083%'	Jared Bradshaw (b) (4)	05 Aug 2020 04:16:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:16:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'chronic obstructive pulmonary disease'	Jared Bradshaw (b) (4)	05 Aug 2020 04:16:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '3'	Jared Bradshaw (b) (4)	05 Aug 2020 04:16:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'mL (mL)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:16:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:16:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'as needed (PRN)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:16:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:16:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jared Bradshaw (b) (4)	05 Aug 2020 04:16:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:16:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		05 Aug 2020 17:40:39
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.'	Jared Bradshaw (b) (4)	05 Aug 2020 04:16:30
answered with 'Per the CRF, all con meds must be entered. Please fix EDC' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 04:16:23
User entered 'un UNK 2010'	Jared Bradshaw (b) (4)	05 Aug 2020 04:16:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '0'	Jared Bradshaw (b) (4)	05 Aug 2020 04:16:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:16:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:16:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:16:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 04:16:23

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 04:16:23

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 04:16:23

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:29:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:29:09
Data point term sent to Coder	System	05 Aug 2020 04:18:17
User entered 'oxygen'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:17:23

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:17:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'chronic obstructive pulmonary disease'	Jared Bradshaw (b) (4)	05 Aug 2020 04:17:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '3'	Jared Bradshaw (b) (4)	05 Aug 2020 04:17:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Other (OTHER)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:17:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'liters'	Jared Bradshaw (b) (4)	05 Aug 2020 04:17:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'as needed (PRN)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:17:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:17:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jared Bradshaw (b) (4)	05 Aug 2020 04:17:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:17:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		05 Aug 2020 17:40:49
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.'	Jared Bradshaw (b) (4)	05 Aug 2020 04:24:53
answered with 'Per the CRF, all con meds must be entered. Please fix EDC' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 04:17:23
User entered 'un UNK 2010'	Jared Bradshaw (b) (4)	05 Aug 2020 04:17:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered '0'	Jared Bradshaw (b) (4)	05 Aug 2020 04:17:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:17:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:17:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:31
User entered 'No (N)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:17:23
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 04:17:23

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 04:17:23

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 04:17:23

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:03
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)	11 Sep 2020 20:17:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 20:17:40
Data point term sent to Coder Coding entries removed.	System Cynthia Kunakom (b) (4)	11 Sep 2020 20:17:11 11 Sep 2020 20:17:07
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)	08 Sep 2020 19:19:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 19:19:51
Data point term sent to Coder User entered 'Acetaminophen'	System Cynthia Kunakom (b) (4)	08 Sep 2020 19:18:44 08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:05
User entered 'No (N)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:07
User entered 'Acute myocardial infarction' reason for change: New Information	Cynthia Kunakom (b) (4)	11 Sep 2020 20:17:07
User entered 'Anterior chest wall pain'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:08
User entered '325'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'mg (mg)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered empty.	Cynthia Kunakom (b) (4)	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'as needed (PRN)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered empty.	Cynthia Kunakom (b) (4)	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered empty.	Cynthia Kunakom (b) (4)	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered '07 Sep 2020'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered '0'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'No (N)' reason for change: New Information	Cynthia Kunakom (b) (4)	11 Sep 2020 20:17:07
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered '07 Sep 2020' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	11 Sep 2020 20:17:07
User entered empty.	Cynthia Kunakom (b) (4)	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'No (N)'	Cynthia Kunakom (b) (4)	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User entered empty.	System	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User entered empty.	System	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:24
User entered empty.	System	08 Sep 2020 19:18:07

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:18:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:18:43
Data point term sent to Coder	System	11 Sep 2020 20:18:12
User entered 'Atorvastatin'	Cynthia Kunakom (b) (4) (b) (4)	11 Sep 2020 20:18:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'No (N)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:03
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'Hyperlipidemia'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:03
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered '40'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:03
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'mg (mg)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:03
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:03
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'once daily (QD)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:03
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:03
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:03
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:03
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User closed query 'Per DM CLR: Con Med ATORVASTATIN was added/changed on 11 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. '(Site from DM). Query 'Per DM CLR: Con Med ATORVASTATIN was added/changed on 11 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'No worsening. Dr did not know which med had caused her rash, so stopped several meds and started others' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:18:06
User opened query 'Per DM CLR: Con Med ATORVASTATIN was added/changed on 11 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. '(Site from DM).	(b) (4), (b) (6)	10 Nov 2020 02:37:32
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered '11 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	11 Sep 2020 20:18:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered '0'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:03
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:03
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	01 Oct 2020 23:17:40
User closed query 'Riverside Community Hospital records note the subject is taking this for 30 days, please flag the source to update the stop date. thank you.' (Site from CRA).	Judith Kirstein (b) (4)	29 Sep 2020 23:56:37
Query 'Riverside Community Hospital records note the subject is taking this for 30 days, please flag the source to update the stop date. thank you.' answered with 'It is a chronic med with no stop date.' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 20:41:07
User opened query 'Riverside Community Hospital records note the subject is taking this for 30 days, please flag the source to update the stop date. thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 00:30:13
DataPoint Verified.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:03
User entered empty.	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'No (N)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:03
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 20:18:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 20:18:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 20:18:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
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)	11 Sep 2020 20:19:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:19:45
Data point term sent to Coder	System	11 Sep 2020 20:19:14
User entered 'carvedilol'	Cynthia Kunakom (b) (4) (b) (4)	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be removed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:40:57
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be removed as appropriate. Otherwise, provide clarification.' answered with 'Corrected' (Site from DM).	Judith Kirstein (b) (4)	03 Oct 2020 21:28:57
DataPoint Un-verified.	Judith Kirstein (b) (4)	03 Oct 2020 21:28:46
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	03 Oct 2020 21:28:46
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be removed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 07:53:50
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'Coronary artery disease'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered '3.125'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'mg (mg)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'twice daily (BID)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered '11 Sep 2020'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered '0'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	23 Sep 2020 14:54:53
User entered 'No (N)' reason for change: New Information	Cynthia Kunakom (b) (4)	23 Sep 2020 14:54:53
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
Query 'Riverside Community Hospital records note the subject is taking this for 30 days, please flag the source to update the stop date. thank you.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 20:43:59
User opened query 'Riverside Community Hospital records note the subject is taking this for 30 days, please flag the source to update the stop date. thank you.' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 20:40:27
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	23 Sep 2020 14:54:53
User entered '21 Sep 2020' reason for change: New Information	Cynthia Kunakom (b) (4)	23 Sep 2020 14:54:53
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'No (N)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User entered '2'	System	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User entered '1'	System	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:45:06
User entered '804 (804)'	System	11 Sep 2020 20:18:49

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	16 Sep 2020 00:30:13
DataPoint Verified.		
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 20:21:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 20:21:40
Data point term sent to Coder	System	11 Sep 2020 20:20:15
User entered 'ticagrelor'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:29
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:29
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'Coronary artery disease'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:29
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered '90'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:29
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'mg (mg)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:29
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:29
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'twice daily (BID)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:29
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:29
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:29
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:29
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered '11 Sep 2020'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:29
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered '0'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:29
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:29
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
User closed query 'Riverside Community Hospital records note the subject is taking this for 30 days, please flag the source to update the stop date. thank you.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 23:18:11
Query 'Riverside Community Hospital records note the subject is taking this for 30 days, please flag the source to update the stop date. thank you.' answered with 'It is a chronic med with no stop date' (Site from CRA).	Judith Kirstein (b) (4)	29 Sep 2020 23:57:07
User opened query 'Riverside Community Hospital records note the subject is taking this for 30 days, please flag the source to update the stop date. thank you.' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 20:39:34
Query 'Riverside Community Hospital records note the subject is taking this for 60 days, please flag the source to update the stop date. thank you.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 20:39:05
User opened query 'Riverside Community Hospital records note the subject is taking this for 60 days, please flag the source to update the stop date. thank you.' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 20:38:16
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:29
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:30:13
User entered 'No (N)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:29
	(b) (4)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Sep 2020 20:19:29

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 20:19:29

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 20:19:29

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:36:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:36:52
Data point term sent to Coder	System	22 Sep 2020 02:52:47
User entered 'Morphine sulfate'	Judith Kirstein (b) (4)	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'Acute myocardial infarction'	Judith Kirstein (b) (4)	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '2'	Judith Kirstein (b) (4)	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'mg (mg)'	Judith Kirstein (b) (4)	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'Intravenous (INTRAVENOUS)'	Judith Kirstein (b) (4)	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '8 Sep 2020'	Judith Kirstein (b) (4)	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '0'	Judith Kirstein (b) (4)	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '8 Sep 2020'	Judith Kirstein (b) (4)	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User entered empty.	System	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User entered empty.	System	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:12
User entered empty.	System	22 Sep 2020 02:51:45

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
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)	22 Sep 2020 05:18:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 05:18:59
Data point term sent to Coder	System	22 Sep 2020 02:53:48
User entered 'Heparin'	Judith Kirstein (b) (4)	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'Acute myocardial infarction'	Judith Kirstein (b) (4)	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '4400'	Judith Kirstein (b) (4)	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'IU (IU)'	Judith Kirstein (b) (4)	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Judith Kirstein (b) (4)	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '8 Sep 2020'	Judith Kirstein (b) (4)	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '0'	Judith Kirstein (b) (4)	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '8 Sep 2020'	Judith Kirstein (b) (4)	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User entered empty.	System	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User entered empty.	System	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:16
User entered empty.	System	22 Sep 2020 02:53:14

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
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)	22 Sep 2020 05:18:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 05:18:59
Data point term sent to Coder	System	22 Sep 2020 02:55:50
User entered 'Heparin infusion (drip) 25,000 IU in 250 ml D5W'	Judith Kirstein (b) (4)	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'Acute myocardial infarction'	Judith Kirstein (b) (4)	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '8.7'	Judith Kirstein (b) (4)	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'Other (OTHER)'	Judith Kirstein (b) (4)	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'ml/hour'	Judith Kirstein (b) (4)	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Judith Kirstein (b) (4)	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '8 Sep 2020'	Judith Kirstein (b) (4)	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '0'	Judith Kirstein (b) (4)	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '8 Sep 2020'	Judith Kirstein (b) (4)	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User entered empty.	System	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User entered empty.	System	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:46:21
User entered empty.	System	22 Sep 2020 02:55:36

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:45:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:45:53
Data point term sent to Coder	System	22 Sep 2020 02:57:51
User entered 'Nitroglycerin'	Judith Kirstein (b) (4)	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'Acute myocardial infarction'	Judith Kirstein (b) (4)	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '0.4'	Judith Kirstein (b) (4)	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'mg (mg)'	Judith Kirstein (b) (4)	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:58:54
User closed query 'Per previous query, subject only takes med as needed. Please update frequency to indicate this frequency as PRN, thank you!' (Site from CRA).	(b) (4), (b) (6)	02 Oct 2020 18:58:52
Query 'Per previous query, subject only takes med as needed. Please update frequency to indicate this frequency as PRN, thank you!' answered with 'Corrected' (Site from CRA).	Judith Kirstein (b) (4)	02 Oct 2020 01:30:08
DataPoint Un-verified.	Judith Kirstein (b) (4)	02 Oct 2020 01:29:27
User entered 'as needed (PRN)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	02 Oct 2020 01:29:27
User opened query 'Per previous query, subject only takes med as needed. Please update frequency to indicate this frequency as PRN, thank you!' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 23:20:29
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'Other (OTHER)'	Judith Kirstein (b) (4)	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'sublingual'	Judith Kirstein (b) (4)	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '8 Sep 2020'	Judith Kirstein (b) (4)	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '0'	Judith Kirstein (b) (4)	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
DataPoint Un-verified.	Judith Kirstein (b) (4)	02 Oct 2020 01:29:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	02 Oct 2020 01:29:27
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
	(b) (4), (b) (6)	
DataPoint Un-verified.	Judith Kirstein (b) (4)	02 Oct 2020 01:29:27
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	Judith Kirstein (b) (4)	02 Oct 2020 01:29:27
	(b) (4), (b) (6)	
User closed query 'Riverside Community Hospital discharge records note Nitroglycerin is taken for 20 days, with no refills. Please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 23:19:27
	(b) (4), (b) (6)	
Query 'Riverside Community Hospital discharge records note Nitroglycerin is taken for 20 days, with no refills. Please verify. Thank you.' answered with 'Nitro is a PRN med only, and she has not had to use any of it.' (Site from CRA).	Judith Kirstein (b) (4)	29 Sep 2020 23:03:51
	(b) (4), (b) (6)	
User opened query 'Riverside Community Hospital discharge records note Nitroglycerin is taken for 20 days, with no refills. Please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 20:36:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
	(b) (4), (b) (6)	
User entered '8 Sep 2020'	Judith Kirstein (b) (4)	22 Sep 2020 02:57:04
	(b) (4), (b) (6)	

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 02:57:04

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
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)	22 Sep 2020 04:59:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 04:59:47
Data point term sent to Coder	System	22 Sep 2020 02:58:51
User entered 'Aspirin'	Judith Kirstein (b) (4)	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'Acute myocardial infarction'	Judith Kirstein (b) (4)	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '325'	Judith Kirstein (b) (4)	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'mg (mg)'	Judith Kirstein (b) (4)	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4)	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '8 Sep 2020'	Judith Kirstein (b) (4)	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '0'	Judith Kirstein (b) (4)	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '8 Sep 2020'	Judith Kirstein (b) (4)	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User entered empty.	System	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User entered empty.	System	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:29
User entered empty.	System	22 Sep 2020 02:58:11

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User closed query 'Source Documents note the subject was instructed to take 400mg of ibuprofen for redness at the injection site on 30 Aug 2020. Please verify and update EDC if applicable. Thank you. (No AE to be entered because it was during the first 7 days post injection).' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 23:21:25
Query 'Source Documents note the subject was instructed to take 400mg of ibuprofen for redness at the injection site on 30 Aug 2020. Please verify and update EDC if applicable. Thank you. (No AE to be entered because it was during the first 7 days post injection).' answered with 'She did not end up taking it' (Site from CRA).	Judith Kirstein (b) (4)	29 Sep 2020 22:58:56
User opened query 'Source Documents note the subject was instructed to take 400mg of ibuprofen for redness at the injection site on 30 Aug 2020. Please verify and update EDC if applicable. Thank you. (No AE to be entered because it was during the first 7 days post injection).' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 20:14:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:47:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:47:48
Data point term sent to Coder	System	22 Sep 2020 02:59:52
User entered 'Ondansetron'	Judith Kirstein (b) (4)	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'Nausea due to acute myocardial infarction'	Judith Kirstein (b) (4)	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '4'	Judith Kirstein (b) (4)	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'mg (mg)'	Judith Kirstein (b) (4)	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'Intravenous (INTRAVENOUS)'	Judith Kirstein (b) (4)	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '8 Sep 2020'	Judith Kirstein (b) (4)	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '0'	Judith Kirstein (b) (4)	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered '8 Sep 2020'	Judith Kirstein (b) (4)	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:00:53
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User entered empty.	System	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User entered empty.	System	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:33
User entered empty.	System	22 Sep 2020 02:59:25

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:16:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 00:17:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 00:17:42
Data point term sent to Coder	System	30 Sep 2020 00:14:51
User entered 'Tramadol'	Judith Kirstein (b) (4)	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:16:22
User entered 'No (N)'	Judith Kirstein (b) (4)	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:16:22
User entered 'Acute myocardial infarction'	Judith Kirstein (b) (4)	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:16:22
User entered '50'	Judith Kirstein (b) (4)	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:16:22
User entered 'mg (mg)'	Judith Kirstein (b) (4)	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:16:22
User entered empty.	Judith Kirstein (b) (4)	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:16:22
User entered 'as needed (PRN)'	Judith Kirstein (b) (4)	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:16:22
User entered empty.	Judith Kirstein (b) (4)	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:16:22
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4)	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:16:22
User entered empty.	Judith Kirstein (b) (4)	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:16:22
User entered '7 Sep 2020'	Judith Kirstein (b) (4)	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:16:22
User entered '0'	Judith Kirstein (b) (4)	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:16:22
User entered 'No (N)'	Judith Kirstein (b) (4)	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:16:22
User entered '8 Sep 2020'	Judith Kirstein (b) (4)	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:16:22
User entered 'No (N)'	Judith Kirstein (b) (4)	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User entered empty.	System	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User entered empty.	System	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:38
User entered empty.	System	30 Sep 2020 00:14:47

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
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)	20 Oct 2020 15:28:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 15:28:37
Data point term sent to Coder	System	20 Oct 2020 15:27:49
User entered 'influenza vaccine'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
User entered 'Influenza prevention'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
User entered '0.5'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
User entered 'mL (mL)'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
User entered empty.	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
User entered 'once (ONCE)'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
User entered empty.	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
User entered 'Intramuscular (INTRAMUSCULAR)'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
User entered empty.	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
User entered '15 Oct 2020'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
User entered '0'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
User entered 'No (N)'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
User entered '15 Oct 2020'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:54:50
User entered 'No (N)'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User entered empty.	System	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User entered empty.	System	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:48:44
User entered empty.	System	20 Oct 2020 15:27:03

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 06:59:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 01:18:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 01:18:02
	(b) (4)	
Data point term sent to Coder	System	26 Nov 2020 01:16:55
User entered 'Plavix'	Jessica Fisher (b) (4)	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 06:59:09
User entered 'No (N)'	Jessica Fisher (b) (4)	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 06:59:11
User entered 'coronary artery disease'	Jessica Fisher (b) (4)	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 06:59:13
User entered '75'	Jessica Fisher (b) (4)	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 06:59:15
User entered 'mg (mg)'	Jessica Fisher (b) (4)	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 06:59:16
User entered empty.	Jessica Fisher (b) (4)	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 06:59:18
User entered 'once daily (QD)'	Jessica Fisher (b) (4)	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 06:59:20
User entered empty.	Jessica Fisher (b) (4)	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 06:59:22
User entered 'Oral (ORAL)'	Jessica Fisher (b) (4)	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 06:59:23
User entered empty.	Jessica Fisher (b) (4)	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 06:59:25
User entered '10 Nov 2020'	Jessica Fisher (b) (4)	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 06:59:26
User entered '0'	Jessica Fisher (b) (4)	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 06:59:28
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 06:59:30
User entered empty.	Jessica Fisher (b) (4)	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 06:59:32
User entered 'No (N)'	Jessica Fisher (b) (4)	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Nov 2020 01:16:46

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:56:45
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)	23 Mar 2021 02:59:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 02:59:30
Data point term sent to Coder	System	23 Mar 2021 02:58:54
User entered 'Triamterene/hydrochlorothiazide'	Jessica Fisher (b) (4)	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:56:45
User entered 'No (N)'	Jessica Fisher (b) (4)	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:56:45
User entered 'bilateral lower extremity edema'	Jessica Fisher (b) (4)	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:56:45
User entered '37.5/25'	Jessica Fisher (b) (4)	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:56:45
User entered 'mg (mg)'	Jessica Fisher (b) (4)	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:56:45
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:56:45
User entered 'once daily (QD)'	Jessica Fisher (b) (4)	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:56:45
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:56:45
User entered 'Oral (ORAL)'	Jessica Fisher (b) (4)	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:56:45
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:56:45
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	23 Mar 2021 02:58:18
User entered '15 Dec 2020' reason for change: Data Entry Error	Jessica Fisher (b) (4)	23 Mar 2021 02:58:18
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	23 Mar 2021 02:57:55
User entered '15 Dec 2021'	Jessica Fisher (b) (4)	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:56:45
User entered '0'	Jessica Fisher (b) (4)	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:56:45
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

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
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:56:45
User entered empty.	Jessica Fisher (b) (4)	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:56:45
User entered 'No (N)'	Jessica Fisher (b) (4)	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:23:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 02:57:55

US3162003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:23:27

[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 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:21:52
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:47
User entered 'Yes (Y)' reason for change: New Information	Cynthia Kunakom (b) (4)	11 Sep 2020 20:19:47
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:58:56
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 19:18:43

US3162003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:23:27

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:22:08
User entered '09 Sep 2020'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:20:03
	(b) (4)	

US3162003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:23:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:19:49
DataPoint Un-verified.	Judith Kirstein (b) (4)	22 Sep 2020 23:23:36
User entered 'BALLOON ANGIOPLASTY OF MID-RIGHT CORONARY ARTERY' reason for change: Data Entry Error	Judith Kirstein (b) (4)	22 Sep 2020 23:23:36
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:22:08
User entered 'Balloon Angioplasty'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:20:03
	(b) (4)	

US3162003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:22:08
User entered 'Adverse Event (AE)'	Cynthia Kunakom (b) (4)	11 Sep 2020 20:20:03
	(b) (4)	

US3162003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:23:27

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:22:08
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 20:20:03
	(b) (4)	

US3162003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:23:27

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:19:49
User entered '9 Sep 2020'	Judith Kirstein (b) (4)	22 Sep 2020 23:22:13

US3162003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:23:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:19:49
User entered 'Left heart catheterization'	Judith Kirstein (b) (4)	22 Sep 2020 23:22:13

US3162003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:19:49
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4)	22 Sep 2020 23:22:13

US3162003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:23:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:20
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:19:49
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 23:22:13

US3162003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:23:27

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:23
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:19:49
User entered '9 Sep 2020'	Judith Kirstein (b) (4)	22 Sep 2020 23:22:57

US3162003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:23:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:23
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:19:49
User entered 'Left and right coronary angiography'	Judith Kirstein (b) (4)	22 Sep 2020 23:22:57

US3162003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:23:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:23
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:19:49
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4)	22 Sep 2020 23:22:57

US3162003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:23:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:23
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:19:49
User entered empty.	Judith Kirstein (b) (4)	22 Sep 2020 23:22:57

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'USA-US074-2020-MRNA-1273-P301000004'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'Yes (Y)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
Un-reviewed for Safety.	System	16 Sep 2020 19:56:47
User entered 'Yes (Y)'	System	16 Sep 2020 19:56:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'Yes (Y)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Judith'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Kirstein'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Banning'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'CA'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered '92220'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:07:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 20:02:35
User entered 'US' (non-conformant).	System	11 Sep 2020 00:25:20

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered '6'	System	15 Oct 2020 12:57:12
User entered '5'	System	06 Oct 2020 16:13:53
User entered '4'	System	23 Sep 2020 16:31:07
User entered '3'	System	17 Sep 2020 12:39:16
User entered '2'	System	12 Sep 2020 20:02:47
User entered '1'	System	11 Sep 2020 00:25:20

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'USA-US074-2020-MRNA-1273-P301000004'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'Yes (Y)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
Un-reviewed for Safety.	System	16 Sep 2020 19:56:47
User entered 'Yes (Y)'	System	16 Sep 2020 19:56:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'Yes (Y)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Judith'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Kirstein'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Banning'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'CA'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered '92220'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:07:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 20:02:35
User entered 'US' (non-conformant).	System	11 Sep 2020 00:25:20

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered '6'	System	15 Oct 2020 12:57:12
User entered '5'	System	06 Oct 2020 16:13:53
User entered '4'	System	23 Sep 2020 16:31:07
User entered '3'	System	17 Sep 2020 12:39:16
User entered '2'	System	12 Sep 2020 20:02:47
User entered '1'	System	11 Sep 2020 00:25:20

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:23:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
User entered '10/Sep/2020 20:25'	System	11 Sep 2020 00:25:20

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:23:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 20:02:35
User entered 'I'	(b) (4), (b) (6)	11 Sep 2020 00:25:20

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'USA-US074-2020-MRNA-1273-P301000004'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'Yes (Y)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
Un-reviewed for Safety.	System	16 Sep 2020 19:56:47
User entered 'Yes (Y)'	System	16 Sep 2020 19:56:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'Yes (Y)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Judith'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Kirstein'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Banning'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'CA'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered '92220'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:07:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 20:02:35
User entered 'US' (non-conformant).	System	11 Sep 2020 00:25:20

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered '6'	System	15 Oct 2020 12:57:12
User entered '5'	System	06 Oct 2020 16:13:53
User entered '4'	System	23 Sep 2020 16:31:07
User entered '3'	System	17 Sep 2020 12:39:16
User entered '2'	System	12 Sep 2020 20:02:47
User entered '1'	System	11 Sep 2020 00:25:20

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:23:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
User entered '12/Sep/2020 16:02'	System	12 Sep 2020 20:02:47

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:23:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'I'	(b) (4), (b) (6)	12 Sep 2020 20:02:47

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'USA-US074-2020-MRNA-1273-P301000004'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'Yes (Y)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
Un-reviewed for Safety.	System	16 Sep 2020 19:56:47
User entered 'Yes (Y)'	System	16 Sep 2020 19:56:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'Yes (Y)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Judith'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Kirstein'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Banning'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'CA'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered '92220'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:07:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 20:02:35
User entered 'US' (non-conformant).	System	11 Sep 2020 00:25:20

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered '6'	System	15 Oct 2020 12:57:12
User entered '5'	System	06 Oct 2020 16:13:53
User entered '4'	System	23 Sep 2020 16:31:07
User entered '3'	System	17 Sep 2020 12:39:16
User entered '2'	System	12 Sep 2020 20:02:47
User entered '1'	System	11 Sep 2020 00:25:20

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:23:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
User entered '17/Sep/2020 08:39'	System	17 Sep 2020 12:39:16

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:23:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:30:54
User entered 'I'	(b) (4), (b) (6)	17 Sep 2020 12:39:16

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'USA-US074-2020-MRNA-1273-P301000004'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'Yes (Y)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
Un-reviewed for Safety.	System	16 Sep 2020 19:56:47
User entered 'Yes (Y)'	System	16 Sep 2020 19:56:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'Yes (Y)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Judith'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Kirstein'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Banning'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'CA'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered '92220'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:07:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 20:02:35
User entered 'US' (non-conformant).	System	11 Sep 2020 00:25:20

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered '6'	System	15 Oct 2020 12:57:12
User entered '5'	System	06 Oct 2020 16:13:53
User entered '4'	System	23 Sep 2020 16:31:07
User entered '3'	System	17 Sep 2020 12:39:16
User entered '2'	System	12 Sep 2020 20:02:47
User entered '1'	System	11 Sep 2020 00:25:20

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:23:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
User entered '23/Sep/2020 12:31'	System	23 Sep 2020 16:31:07

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:23:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 16:13:34
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 16:31:07

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'USA-US074-2020-MRNA-1273-P301000004'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'Yes (Y)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
Un-reviewed for Safety.	System	16 Sep 2020 19:56:47
User entered 'Yes (Y)'	System	16 Sep 2020 19:56:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'Yes (Y)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Judith'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Kirstein'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Banning'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'CA'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered '92220'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:07:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 20:02:35
User entered 'US' (non-conformant).	System	11 Sep 2020 00:25:20

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered '6'	System	15 Oct 2020 12:57:12
User entered '5'	System	06 Oct 2020 16:13:53
User entered '4'	System	23 Sep 2020 16:31:07
User entered '3'	System	17 Sep 2020 12:39:16
User entered '2'	System	12 Sep 2020 20:02:47
User entered '1'	System	11 Sep 2020 00:25:20

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:23:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:10:33
User entered '06/Oct/2020 16:13'	System	06 Oct 2020 16:13:53

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:23:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:10:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:57:00
User entered 'I'	(b) (4), (b) (6)	06 Oct 2020 16:13:53

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'USA-US074-2020-MRNA-1273-P301000004'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'Yes (Y)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
Un-reviewed for Safety.	System	16 Sep 2020 19:56:47
User entered 'Yes (Y)'	System	16 Sep 2020 19:56:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'Yes (Y)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:25:14
User entered 'No (N)'	System	11 Sep 2020 00:24:27

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Judith'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Kirstein'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'Banning'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered 'CA'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:39:05
User entered '92220'	Judith Kirstein (b) (4)	13 Sep 2020 16:02:05

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 21:02:53
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:07:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 20:02:35
User entered 'US' (non-conformant).	System	11 Sep 2020 00:25:20

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
User entered '6'	System	15 Oct 2020 12:57:12
User entered '5'	System	06 Oct 2020 16:13:53
User entered '4'	System	23 Sep 2020 16:31:07
User entered '3'	System	17 Sep 2020 12:39:16
User entered '2'	System	12 Sep 2020 20:02:47
User entered '1'	System	11 Sep 2020 00:25:20

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:23:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:10:39
User entered '15/Oct/2020 12:57'	System	15 Oct 2020 12:57:12

US3162003

Folder: SAE USA-US074-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:23:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

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DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:10:42
User entered 'I'	(b) (4), (b) (6)	15 Oct 2020 12:57:12