

US3162090 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:28:50

All time stamps listed in this document are displayed in GMT

US3162090

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

[Participant ID](#)

US3162090

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

US3162090

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3162090

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Date of Informed Consent (*dd MMM yyyy*) 10 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

US3162090

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3162090

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Were any significant conditions reported?

Yes ☒

No ☐

US3162090

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3162090

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3162090

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Condition	MALE PATTERN BALDNESS
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

US3162090

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Condition	RECURRENT SINUSITIS
Start date (dd MMM yyyy)	UN UNK 1979
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1979
Start Year (derived)	1979
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

US3162090

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Condition	PANIC ATTACKS
Start date (dd MMM yyyy)	UN JUL 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3162090

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1979
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 1979
Start Year (derived)	1979
Stop Month and Year (derived)	
Stop Year (derived)	

US3162090

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:58 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 13:58
Height (<i>xxx.x</i>)	74 in
Weight (<i>xxx.x</i>)	180 lb
BMI (<i>xxx.x</i>)	23.15895 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162090

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

US3162090

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3162090

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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

Visit date (dd MMM yyyy)	10 AUG 2020
--------------------------	-------------

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

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

US3162090

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 185127

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☐

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Height	ND - Not Done
Weight	ND - Not Done

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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)	10 AUG 2020
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 13:50
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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)	10 AUG 2020
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 15:15
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3162090

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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.

US3162090

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 10 AUG 2020

What was the treatment time? (00:00-23:59) 14:40 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 14:40

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

US3162090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 10 AUG 2020

Collection time (00:00-23:59) 14:15 (24 HR)

Collection date and time (derived) 10 AUG 2020 14:15

US3162090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:17	10 AUG 2020 14:17
Nasopharyngeal Swab 2	No		

US3162090

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

10 AUG 2020 15:25

PC Open Date & Time

10 AUG 2020 15:00

PC Close Date & Time

10 AUG 2020 17:30

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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

98.8 °F

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

Yes ☐
No ☒

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

PC Time Stamp	10 AUG 2020 19:32
PC Open Date & Time	10 AUG 2020 18:25
PC Close Date & Time	11 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 21:05

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 16:40

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

13 AUG 2020 22:03

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:50

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

98.6 °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

14 AUG 2020 16:40

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 15:42

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

16 AUG 2020 20:12

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 15:27

PC Open Date & Time

10 AUG 2020 15:00

PC Close Date & Time

10 AUG 2020 17:30

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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

10 AUG 2020 19:33

PC Open Date & Time

10 AUG 2020 18:25

PC Close Date & Time

11 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

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

11 AUG 2020 21:06

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

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

12 AUG 2020 16:41

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

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

13 AUG 2020 22:04

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

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

14 AUG 2020 16:40

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

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

15 AUG 2020 15:42

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

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

16 AUG 2020 20:13

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 15:29
PC Open Date & Time	10 AUG 2020 15:00
PC Close Date & Time	10 AUG 2020 17:30

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 19:34
PC Open Date & Time	10 AUG 2020 18:25
PC Close Date & Time	11 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

47 of 2595

EAB) (1725)

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 21:07
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

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

49 of 2595

EAB) (1725)

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 16:42
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

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

51 of 2595

EAB) (1725)

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 22:05
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

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 ☒

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 16:41
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

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

55 of 2595

EAB) (1725)

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 15:43
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

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 ☒

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 20:14
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3162090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162090

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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	VISIT2

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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)	8 SEP 2020
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 14:40
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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)	8 SEP 2020
Time of assessment (00:00-23:59)	17:00 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 17:00
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3162090

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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.

US3162090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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) 8 SEP 2020

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

Treatment Date and Time (derived) 8 SEP 2020 16:23

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

US3162090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 SEP 2020
Collection time (00:00-23:59)	15:14 (24 HR)
Collection date and time (derived)	8 SEP 2020 15:14

US3162090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:18	8 SEP 2020 15:18
Nasopharyngeal Swab 2	No		

US3162090

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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

97.5 °F

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

Yes ☐
No ☒

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

PC Time Stamp

08 SEP 2020 17:03

PC Open Date & Time

08 SEP 2020 16:43

PC Close Date & Time

08 SEP 2020 19:13

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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 97.3 °F

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

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

PC Time Stamp	08 SEP 2020 22:02
PC Open Date & Time	08 SEP 2020 20:08
PC Close Date & Time	09 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 09:59

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:50

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 22:12

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 22:13

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:50

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 20:57

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:50

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

97.7 °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

13 SEP 2020 22:21

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 20:02

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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

08 SEP 2020 17:05

PC Open Date & Time

08 SEP 2020 16:43

PC Close Date & Time

08 SEP 2020 19:13

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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

08 SEP 2020 22:03

PC Open Date & Time

08 SEP 2020 20:08

PC Close Date & Time

09 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

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

10 SEP 2020 10:00

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

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

10 SEP 2020 22:12

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

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

11 SEP 2020 22:14

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

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

12 SEP 2020 20:58

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

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

13 SEP 2020 22:21

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

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

14 SEP 2020 20:02

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 17:06
PC Open Date & Time	08 SEP 2020 16:43
PC Close Date & Time	08 SEP 2020 19:13

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 22:04
PC Open Date & Time	08 SEP 2020 20:08
PC Close Date & Time	09 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

93 of 2595

EAB) (1725)

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 10:00
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

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

95 of 2595

EAB) (1725)

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 22:13
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

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

97 of 2595

EAB) (1725)

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 22:14
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

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

99 of 2595

EAB) (1725)

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 20:58
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

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 ☒

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 22:22
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

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

103 of 2595

EAB) (1725)

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 20:03
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3162090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3162090

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3162090

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3162090

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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

Visit date (dd MMM yyyy)	6 OCT 2020
--------------------------	------------

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

Folder OID	VISIT3
------------	--------

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	6 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:52 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 12:52
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	11 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	88 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	55 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162090

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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.

US3162090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 OCT 2020
Collection time (00:00-23:59)	13:23 (24 HR)
Collection date and time (derived)	6 OCT 2020 13:23

US3162090

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 OCT 2020 00:04:25
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

18 OCT 2020 15:09:23

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

24 OCT 2020 23:29:38

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

07 NOV 2020 07:56:55

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 NOV 2020 22:10:10
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 21:00:14

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

25 NOV 2020 20:34:24

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

02 DEC 2020 22:41:29

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 12:11:35
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

16 DEC 2020 23:40:05

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

24 DEC 2020 12:49:47

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

02 JAN 2021 18:20:42

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

08 JAN 2021 11:51:42

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

15 JAN 2021 16:28:13

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 23:09:04

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

27 JAN 2021 23:38:25

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 00:14:12
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

10 FEB 2021 07:23:26

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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	17 FEB 2021 22:24:28
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 08:08:07
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 16:28:41

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

10 MAR 2021 08:43:27

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

17 MAR 2021 21:42:17

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

24 MAR 2021 23:21:11

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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	02 APR 2021 12:00:26
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

07 APR 2021 08:10:07

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

15 APR 2021 16:44:12

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 APR 2021 11:56:44
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	29 APR 2021 19:56:11
Patient Cloud Open Date & Time	28 APR 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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="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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 320

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

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

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

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

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 <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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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="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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 <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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 <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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

Patient Cloud Open Date & Time	25 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	29 AUG 2021 23:59
---	-------------------

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 <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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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="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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 <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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

Patient Cloud Open Date & Time	27 OCT 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	31 OCT 2021 23:59
---	-------------------

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 <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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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="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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission	
Patient Cloud Open Date & Time	12 JAN 2022 00:01
Patient Cloud Close Date & Time	16 JAN 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 <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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission	
Patient Cloud Open Date & Time	23 FEB 2022 00:01
Patient Cloud Close Date & Time	27 FEB 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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="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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission	
Patient Cloud Open Date & Time	06 APR 2022 00:01
Patient Cloud Close Date & Time	10 APR 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 <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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 <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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 <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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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="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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission	
Patient Cloud Open Date & Time	29 JUN 2022 00:01
Patient Cloud Close Date & Time	03 JUL 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 <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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission	
Patient Cloud Open Date & Time	06 JUL 2022 00:01
Patient Cloud Close Date & Time	10 JUL 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 <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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 <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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

Patient Cloud Open Date & Time	10 AUG 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	14 AUG 2022 23:59
---	-------------------

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	07 SEP 2022 00:01
Patient Cloud Close Date & Time	11 SEP 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission	
Patient Cloud Open Date & Time	14 SEP 2022 00:01
Patient Cloud Close Date & Time	18 SEP 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Patient Cloud Close Date & Time	09 OCT 2022 23:59
---	-------------------

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3162090

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:28:50

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 22:19:00

US3162090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162090

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 7 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3162090

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3162090

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3162090

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 23:02:53

Generated On: 09 Jun 2021 15:28:50

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

Visit date (dd MMM yyyy)	15 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
------------	--------

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 23:02:53

Generated On: 09 Jun 2021 15:28:50

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) _____

US3162090

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 23:02:53

Generated On: 09 Jun 2021 15:28:50

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.

US3162090

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 23:02:53

Generated On: 09 Jun 2021 15:28:50

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

Collection date (dd MMM yyyy)	15 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	10:14 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	15 MAR 2021 10:14
------------------------------------	-------------------

US3162090

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:02:53

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

Date of Contact	11 NOV 2020
Time of Contact	14:25
Date and Time of Contact (derived)	11 NOV 2020 14:25
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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

Date	9 NOV 2020
------	------------

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

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

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

315 of 2595

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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

Date	10 NOV 2020
------	-------------

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

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

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

319 of 2595

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

323 of 2595

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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 type="radio"/>
	Mild	<input checked="" 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"/>

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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

Date	12 NOV 2020
------	-------------

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

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

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

Temperature	98.1 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

327 of 2595

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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

Date	13 NOV 2020
------	-------------

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

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

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

Temperature	97.5 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

331 of 2595

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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

Date	14 NOV 2020
------	-------------

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

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

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

Temperature	97.8 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

335 of 2595

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

336 of 2595

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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

Date	15 NOV 2020
------	-------------

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

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

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

Temperature	97.4 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

339 of 2595

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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"/>

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

Date of Visit	12 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	12 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:28:50

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	14 NOV 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)	

US3162090

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	09:27 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 09:27
Height (xxx.x)	74 in
Weight (xxx.x)	183.4 lb
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162090

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 NOV 2020

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

US3162090

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

12 NOV 2020

US3162090

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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

Visit date (dd MMM yyyy)	18 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
------------	---------------

US3162090

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 23:02:52

Generated On: 09 Jun 2021 15:28:50

Date of updated informed consent (<i>dd MMM yyyy</i>)	18 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	18 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3162090

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Apr 2021 23:02:52

Generated On: 09 Jun 2021 15:28:50

Height	74 in
Weight	180 lb
BMI (xxx.x)	23.15895

US3162090

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 23:02:52

Generated On: 09 Jun 2021 15:28:50

Height	74 in
Weight	180 lb
BMI (xxx.x)	23.15895
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)	18 JAN 2021
Time of assessment (00:00-23:59)	10:50 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 10:50
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3162090

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 23:02:52

Generated On: 09 Jun 2021 15:28:50

Height	74 in
Weight	180 lb
BMI (xxx.x)	23.15895
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)	18 JAN 2021
Time of assessment (00:00-23:59)	12:38 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 12:38
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3162090

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

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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.

US3162090

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

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 18 JAN 2021

What was the treatment time? (00:00-23:59) 12:03 (24 HR)

Treatment Date and Time (derived) 18 JAN 2021 12:03

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

US3162090

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

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

Collection date (dd MMM yyyy)	18 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	10:56 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	18 JAN 2021 10:56
------------------------------------	-------------------

US3162090

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00 - 23:59)	11:02
Collection Date and Time (derived)	18 JAN 2021 11:02

US3162090

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:06:56

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 23:02:53

Generated On: 09 Jun 2021 15:28:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3162090

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:02:53

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 23:02:52

Generated On: 09 Jun 2021 15:28:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 23:02:52

Generated On: 09 Jun 2021 15:28:50

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)	15 FEB 2021
Time of assessment (00:00-23:59)	10:41 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 10:41
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 23:02:52

Generated On: 09 Jun 2021 15:28:50

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)	15 FEB 2021
Time of assessment (00:00-23:59)	11:49 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 11:49
Temperature (xxx.x)	97.7 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)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3162090

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 23:02:52

Generated On: 09 Jun 2021 15:28:50

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.

US3162090

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 24 Apr 2021 23:02:52

Generated On: 09 Jun 2021 15:28:50

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

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

What was the treatment date? (dd MMM yyyy) 15 FEB 2021

What was the treatment time? (00:00-23:59) 11:14 (24 HR)

Treatment Date and Time (derived) 15 FEB 2021 11:14

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

US3162090

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:02:52

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 23:02:53

Generated On: 09 Jun 2021 15:28:50

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162090

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:02:53

Generated On: 09 Jun 2021 15:28:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162090

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 23:02:52

Generated On: 09 Jun 2021 15:28:50

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

Visit date (dd MMM yyyy)	15 MAR 2021
--------------------------	-------------

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

Folder OID	OLD57
------------	-------

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 23:02:52

Generated On: 09 Jun 2021 15:28:50

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) _____

US3162090

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 23:02:52

Generated On: 09 Jun 2021 15:28:50

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.

US3162090

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 23:02:52

Generated On: 09 Jun 2021 15:28:50

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

Collection date (dd MMM yyyy)	15 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	10:14 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	15 MAR 2021 10:14
------------------------------------	-------------------

US3162090

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

AEID

Adverse event

ACUTE VIRAL INFECTION,
UNSPECIFIED

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)

9 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

374 of 2595

EAB) (1725)

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

AEID

Adverse event

BLEEDING INTERNAL
HEMORRHOID

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)

31 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

376 of 2595

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

AEID	
Adverse event	EXERTIONAL CHEST PAIN
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)	1 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

378 of 2595

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

AEID	USA-US074-2021-MRNA-1273-P30 1000022
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)	27 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	27 APR 2021
Hospital Discharge Date (dd MMM yyyy)	29 APR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	380 of 2595

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Number of Days in ICU	2
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	

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

SUBJECT HAD BEEN HAVING
CHEST PAIN WITH EXERTION
SINCE 01APR2021. ON
27APR2021, HE AWOKE WITH
CHEST PAIN, PRESENTED TO
ER, UNDERWENT CORONARY
ARTERY CATHETERIZATION
WHICH SHOWED 100%
OCCLUSION OF LEFT
ANTERIOR DESCENDING
ARTERY. STENT WAS PLACED.
SUBJECT WENT HOME
29APR2021.

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

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

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)	27 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2595

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 01:06:55

Generated On: 09 Jun 2021 15:28:50

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

Yes ☒

No ☐

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

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

386 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	26 APR 2021	
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"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication PROZAC

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

388 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	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)	31 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	12 AUG 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"/>	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication FINASTERIDE

Prophylaxis Yes ☐
No ☒

Indication MALE PATTERN BALDNESS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

390 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	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 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"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication L-LYSINE

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

392 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	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 2012	
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"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 10000

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)

394 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<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"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication VALERIAN

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

396 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<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"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 3

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

398 of 2595

EAB) (1725)

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<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"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication PROZAC

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

400 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 AUG 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"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication PANIC ATTACKS

Dose per administration 0.5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

402 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 AUG 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication L-ARGININE

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 700

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)

404 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	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)		29 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"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication PNEUMOCOCCAL
POLYVALENT VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR
PNEUMOCOCCAL BACTERIA
INFECTION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

406 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 OCT 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"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication ACUTE VIRAL INFECTION,
UNSPECIFIED

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

408 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	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)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication FLONASE NASAL SPRAY

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

410 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication ACETAMINOPHEN/DIPHENHYD
RAMINE

Prophylaxis Yes ☐
No ☒

Indication ACUTE VIRAL INFECTION,
UNSPECIFIED

Dose per administration 1000/50

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)

412 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	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)	14 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 2.5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

414 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	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)	27 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 12.5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

416 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	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)	27 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication RIVAROXABAN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 2.5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

418 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	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)	27 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Name of Medication ROSUVASTATIN

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 ☐

PRODUCTION RELEASE (v12.003

420 of 2595

EAB) (1725)

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	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)	27 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

422 of 2595

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

	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)	27 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162090

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3162090

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
27 APR 2021	CORONARY ARTERY STENT PLACEMENT	Adverse Event	

US3162090

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:28:50

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

US3162090

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:28:50

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 ☐

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

SAEID	USA-US074-2021-MRNA-1273-P301000022
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:50

SAEID	USA-US074-2021-MRNA-1273-P301000022
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	30/APR/2021 09:31
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

Audit

US3162090 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

US3162090

Form: Participant Creation

Generated On: 09 Jun 2021 15:28:50

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'US3162090'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:44:23

US3162090

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 20:10:25

US3162090

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:44:24

US3162090

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Aug 2020 20:10:25

US3162090

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered 'SCRN'	System	12 Aug 2020 20:10:25

US3162090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:50

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:44:25

US3162090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:50

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '66'	(b) (4), (b) (6)	12 Aug 2020 20:10:07

US3162090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:50

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered 'YEARS'	System	12 Aug 2020 20:10:07

US3162090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:50

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered '66'	System	10 Aug 2020 21:47:15

US3162090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:50

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Male (M)'	(b) (4), (b) (6)	12 Aug 2020 20:10:07

US3162090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:50

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	12 Aug 2020 20:10:07

US3162090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:50

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'I'	(b) (4), (b) (6)	12 Aug 2020 20:10:07

US3162090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:50

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:10:07

US3162090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:50

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:10:07

US3162090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:50

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:10:07

US3162090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:50

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:10:07

US3162090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:10:07

US3162090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:50

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:10:07

US3162090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:50

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:10:07

US3162090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:50

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:10:07

US3162090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:50

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '10 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	10 Aug 2020 21:47:15

US3162090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered 'Aug 2020'	System	10 Aug 2020 21:47:15

US3162090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered '2020'	System	10 Aug 2020 21:47:15

US3162090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:50

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Amendment 2 (2)'	Jared Bradshaw (b) (4) (b) (4)	10 Aug 2020 21:47:15

US3162090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	10 Aug 2020 21:47:15

US3162090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	10 Aug 2020 21:47:15

US3162090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:50

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	10 Aug 2020 21:47:15

US3162090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:50

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	10 Aug 2020 21:47:15

US3162090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:50

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:44:24

US3162090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:50

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered 'I'	System	10 Aug 2020 21:47:22

US3162090

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	10 Aug 2020 21:47:22

US3162090

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:28:50

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 18:57:24

US3162090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:01:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:01:13
Data point term sent to Coder	System	12 Aug 2020 19:00:10
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	12 Aug 2020 18:59:41

US3162090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'UN UNK 2018'	(b) (4), (b) (6)	12 Aug 2020 18:59:41

US3162090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 18:59:41

US3162090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 18:59:41

US3162090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 18:59:41

US3162090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 18:59:41

US3162090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered 'Jan 2018'	System	12 Aug 2020 18:59:41

US3162090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered '2018'	System	12 Aug 2020 18:59:41

US3162090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered empty.	System	12 Aug 2020 18:59:41

US3162090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered empty.	System	12 Aug 2020 18:59:41

US3162090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:03:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:03:12
Data point term sent to Coder	System	12 Aug 2020 19:02:14
User entered 'Depression'	(b) (4), (b) (6)	12 Aug 2020 19:01:29

US3162090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'UN UNK 1995'	(b) (4), (b) (6)	12 Aug 2020 19:01:29

US3162090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 19:01:29

US3162090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 19:01:29

US3162090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 19:01:29

US3162090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 19:01:29

US3162090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered 'Jan 1995'	System	12 Aug 2020 19:01:29

US3162090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered '1995'	System	12 Aug 2020 19:01:29

US3162090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered empty.	System	12 Aug 2020 19:01:29

US3162090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered empty.	System	12 Aug 2020 19:01:29

US3162090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Alopecias, PT: Androgenetic alopecia, LLT: Male pattern baldness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:05:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:05:07
Data point term sent to Coder	System	12 Aug 2020 19:04:20
User entered 'Male pattern baldness'	(b) (4), (b) (6)	12 Aug 2020 19:04:06

US3162090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'UN UNK 1999'	(b) (4), (b) (6)	12 Aug 2020 19:04:06

US3162090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 19:04:06

US3162090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 19:04:06

US3162090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 19:04:06

US3162090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 19:04:06

US3162090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered 'Jan 1999'	System	12 Aug 2020 19:04:06

US3162090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered '1999'	System	12 Aug 2020 19:04:06

US3162090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered empty.	System	12 Aug 2020 19:04:06

US3162090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered empty.	System	12 Aug 2020 19:04:06

US3162090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis recurrent - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:46:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:46:19
Data point term sent to Coder	System	12 Aug 2020 19:30:08
User entered 'Recurrent sinusitis'	(b) (4), (b) (6)	12 Aug 2020 19:29:57

US3162090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'UN UNK 1979'	(b) (4), (b) (6)	12 Aug 2020 19:29:57

US3162090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 19:29:57

US3162090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 19:29:57

US3162090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'UN UNK 1995'	(b) (4), (b) (6)	12 Aug 2020 19:29:57

US3162090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 19:29:57

US3162090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered 'Jan 1979'	System	12 Aug 2020 19:29:57

US3162090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered '1979'	System	12 Aug 2020 19:29:57

US3162090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered 'Jan 1995'	System	12 Aug 2020 19:29:57

US3162090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered '1995'	System	12 Aug 2020 19:29:57

US3162090

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Panic attacks and disorders, PT: Panic attack, LLT: Panic attacks - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 00:17:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 00:17:35
Data point term sent to Coder	System	04 Oct 2020 00:16:32
User entered 'Panic attacks'	Judith Kirstein (b) (4) (b) (4)	04 Oct 2020 00:16:13

US3162090

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'UN Jul 2020'	Judith Kirstein (b) (4) (b) (4)	04 Oct 2020 00:16:13

US3162090

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	04 Oct 2020 00:16:13

US3162090

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	04 Oct 2020 00:16:13

US3162090

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	04 Oct 2020 00:16:13

US3162090

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	04 Oct 2020 00:16:13

US3162090

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered 'Jul 2020'	System	04 Oct 2020 00:16:13

US3162090

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered '2020'	System	04 Oct 2020 00:16:13

US3162090

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered empty.	System	04 Oct 2020 00:16:13

US3162090

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered empty.	System	04 Oct 2020 00:16:13

US3162090

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 17:58:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 17:58:45
Data point term sent to Coder	System	16 Nov 2020 17:57:23
User entered 'SEASONAL ALLERGIES'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:56:47

US3162090

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'UN UNK 1979'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:56:47

US3162090

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:56:47

US3162090

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:56:47

US3162090

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:56:47

US3162090

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:56:47

US3162090

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered 'Jan 1979'	System	16 Nov 2020 17:56:47

US3162090

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered '1979'	System	16 Nov 2020 17:56:47

US3162090

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered empty.	System	16 Nov 2020 17:56:47

US3162090

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered empty.	System	16 Nov 2020 17:56:47

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 19:49:04

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '10 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 19:49:04

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '13:58'	(b) (4), (b) (6)	12 Aug 2020 19:49:04

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered '10 Aug 2020 13:58'	System	12 Aug 2020 19:49:04

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '74' in	(b) (4), (b) (6)	12 Aug 2020 19:49:04
DataPoint set to visible.	System	10 Aug 2020 21:47:22

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '180' lb	(b) (4), (b) (6)	12 Aug 2020 19:49:04
DataPoint set to visible.	System	10 Aug 2020 21:47:22

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
Amendment Manager: User entered '23.15895'	System	16 Sep 2020 23:50:45
User entered '23.2'	System	12 Aug 2020 19:49:04
DataPoint set to visible.	System	10 Aug 2020 21:47:22

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered 'kg/m2'	System	12 Aug 2020 19:49:04
DataPoint set to visible.	System	10 Aug 2020 21:47:22

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
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)	14 Sep 2020 17:51:32
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) (b) (4)	11 Sep 2020 02:18:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	11 Sep 2020 02:18:35
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 17:18:16
User entered '98.8' F	(b) (4), (b) (6)	12 Aug 2020 19:49:04

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	11 Sep 2020 02:18:35
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Aug 2020 19:49:04

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 19:49:04

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	11 Sep 2020 02:18:35
User entered '68'	(b) (4), (b) (6)	12 Aug 2020 19:49:04

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered 'bpm'	System	12 Aug 2020 19:49:04

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	11 Sep 2020 02:18:35
User entered '12'	(b) (4), (b) (6)	12 Aug 2020 19:49:04

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered 'breaths/min'	System	12 Aug 2020 19:49:04

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	11 Sep 2020 02:18:35
User entered '114'	(b) (4), (b) (6)	12 Aug 2020 19:49:04

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered 'mmHg'	System	12 Aug 2020 19:49:04

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	11 Sep 2020 02:18:35
User entered '70'	(b) (4), (b) (6)	12 Aug 2020 19:49:04

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User entered 'mmHg'	System	12 Aug 2020 19:49:04

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33

US3162090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33

US3162090

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 19:50:51

US3162090

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 14:25:32
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 03:18:27
User entered '10 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 19:50:51

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:08:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:08:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 20:08:50
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:07:17
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:08:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:08:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 20:08:50
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:07:17
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:08:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:08:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 20:08:50
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:07:17
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:09:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:09:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 20:09:03
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:07:17
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:08:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:08:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 20:08:50
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:07:17
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:08:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:08:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 20:08:50
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:07:17
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:08:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:08:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 20:08:50
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:07:17
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:08:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:08:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 20:08:50
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:07:17
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:08:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:08:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 20:08:50
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:07:17
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:08:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:08:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 20:08:50
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:07:17
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:08:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:08:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 20:08:50
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:07:17
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'I'	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:17

US3162090**Folder: Visit 1 Day 1****Form: Visit Date****Generated On: 09 Jun 2021 15:28:50**[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 17:42:46

US3162090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 17:42:46

US3162090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[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 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Aug 2020 17:42:46

US3162090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'VISIT1'	System	11 Aug 2020 17:42:46

US3162090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 21:29:21

US3162090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:50

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:25:31
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:25:31
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 21:29:21
User entered '185127' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 21:29:21

US3162090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:50

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 21:29:21

US3162090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:50

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 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 17:43:06

US3162090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:50

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 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 17:43:06

US3162090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:50

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 17:43:06

US3162090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:50

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 17:43:06

US3162090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:50

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 17:43:06

US3162090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:50

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:01
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:21:48

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	13 Aug 2020 01:46:57
User entered '74' in	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	13 Aug 2020 01:46:57
User entered '180' lb	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	13 Aug 2020 01:46:57
User entered '74' in	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	13 Aug 2020 01:46:57
User entered '180' lb	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '10 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	12 Aug 2020 21:04:04
User entered '13:50' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 21:04:04
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	12 Aug 2020 20:21:46
User entered '15:14'	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered '10 Aug 2020 13:50'	System	12 Aug 2020 21:04:04
User entered '10 Aug 2020 15:14'	System	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '98.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 21:04:04
User entered '98.7' F	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '68' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 21:04:04
User entered '75'	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'bpm'	System	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '12' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 21:04:04
User entered '13'	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'breaths/min'	System	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '114' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 21:04:04
User entered '115'	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'mmHg'	System	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 21:04:04
User entered '76'	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'mmHg'	System	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	13 Aug 2020 01:46:57
User entered '74' in	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	13 Aug 2020 01:46:57
User entered '180' lb	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '10 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 17:00:34
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).	System	12 Aug 2020 21:04:04
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 21:04:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	12 Aug 2020 21:04:04
User entered '15:15' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 21:04:04
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 20:21:46
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered '10 Aug 2020 15:15'	System	12 Aug 2020 21:04:04
User entered empty.	System	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 21:04:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).		12 Aug 2020 21:04:04
User entered '98.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 21:04:04
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 20:21:46
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 21:04:04
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 21:04:04
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 20:21:46
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 21:04:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).		12 Aug 2020 21:04:04
User entered '75' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 21:04:04
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 20:21:46
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'bpm'	System	12 Aug 2020 21:04:04
User entered empty.	System	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 21:04:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).		12 Aug 2020 21:04:04
User entered '13' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 21:04:04
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 20:21:46
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'breaths/min'	System	12 Aug 2020 21:04:04
User entered empty.	System	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 21:04:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).		12 Aug 2020 21:04:04
User entered '115' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 21:04:04
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 20:21:46
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'mmHg'	System	12 Aug 2020 21:04:04
User entered empty.	System	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 21:04:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).		12 Aug 2020 21:04:04
User entered '76' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 21:04:04
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 20:21:46
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'mmHg'	System	12 Aug 2020 21:04:04
User entered empty.	System	12 Aug 2020 20:21:46

US3162090

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 21:15:14

US3162090

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 21:15:14

US3162090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	10 Aug 2020 21:47:48

US3162090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered empty.	Jared Bradshaw (b) (4)	10 Aug 2020 21:47:48
	(b) (4)	

US3162090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

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 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	10 Aug 2020 21:47:48

US3162090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 21:47:48

US3162090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '10 Aug 2020'	Jared Bradshaw (b) (4)	10 Aug 2020 21:47:48
	(b) (4)	

US3162090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '14:40'	Jared Bradshaw (b) (4)	10 Aug 2020 21:47:48
	(b) (4)	

US3162090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered '10 Aug 2020 14:40'	System	10 Aug 2020 21:47:48

US3162090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Left Arm (LEFT ARM)'	Jared Bradshaw (b) (4) (b) (4)	10 Aug 2020 21:47:48

US3162090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'ONCE'	System	10 Aug 2020 21:47:48

US3162090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 21:47:48

US3162090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 21:18:36

US3162090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '10 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 21:18:36

US3162090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '14:15'	(b) (4), (b) (6)	12 Aug 2020 21:18:36

US3162090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered '10 Aug 2020 14:15'	System	12 Aug 2020 21:18:36

US3162090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:28:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	14 Aug 2020 01:16:59
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	14 Aug 2020 01:16:59
User entered '10 Aug 2020' reason for change: Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	14 Aug 2020 01:16:59
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	12 Aug 2020 21:21:37
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 21:21:37

US3162090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	12 Aug 2020 21:21:37

US3162090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 21:21:37

US3162090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '14:17'	(b) (4), (b) (6)	12 Aug 2020 21:21:37

US3162090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered '10 Aug 2020 14:17'	System	14 Aug 2020 01:16:59
User entered empty.	System	12 Aug 2020 21:21:37

US3162090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	12 Aug 2020 21:21:37

US3162090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 21:21:37

US3162090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:50

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 21:21:37

US3162090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered empty.	System	12 Aug 2020 21:21:37

US3162090

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 21:21:49

US3162090

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'I'	System	12 Aug 2020 21:21:49

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:24:57', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c50300e7-d90e-4e2a-a579-f382a7330a13' User entered 'Yes (Y)'	System	10 Aug 2020 22:25:50
	System	10 Aug 2020 22:25:50

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:25:21', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c50300e7-d90e-4e2a-a579-f382a7330a13' User entered '98.7'	System	10 Aug 2020 22:25:50
	System	10 Aug 2020 22:25:50

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:25:35', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c50300e7-d90e-4e2a-a579-f382a7330a13'	System	10 Aug 2020 22:25:50
User entered 'No (N)'	System	10 Aug 2020 22:25:50

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:25:46', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c50300e7-d90e-4e2a-a579-f382a7330a13' User entered '10 Aug 2020 15:25'	System	10 Aug 2020 22:25:50
	System	10 Aug 2020 22:25:50

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '10 Aug 2020 15:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '10 Aug 2020 17:30'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:31:16', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '2750d08c-937e-4bc6-afa5-4b148d1301cc' User entered 'Yes (Y)'	System	11 Aug 2020 02:32:12
	System	11 Aug 2020 02:32:12

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:31:25', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '2750d08c-937e-4bc6-afa5-4b148d1301cc' User entered '98.8'	System	11 Aug 2020 02:32:12
	System	11 Aug 2020 02:32:12

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:31:34', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '2750d08c-937e-4bc6-afa5-4b148d1301cc' User entered 'No (N)'	System	11 Aug 2020 02:32:12
	System	11 Aug 2020 02:32:12

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:32:09', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '2750d08c-937e-4bc6-afa5-4b148d1301cc' User entered '10 Aug 2020 19:32'	System	11 Aug 2020 02:32:12
	System	11 Aug 2020 02:32:12

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '10 Aug 2020 18:25'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 2'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:50

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:05:02', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '0fce29be-a080-44c3-847a-0922063ac958' User entered 'Yes (Y)'	System	12 Aug 2020 04:05:39
	System	12 Aug 2020 04:05:39

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:05:11', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '0fce29be-a080-44c3-847a-0922063ac958' User entered '98.0'	System	12 Aug 2020 04:05:39
	System	12 Aug 2020 04:05:39

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:05:19', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '0fce29be-a080-44c3-847a-0922063ac958'	System	12 Aug 2020 04:05:39
User entered 'No (N)'	System	12 Aug 2020 04:05:39

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:05:37', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '0fce29be-a080-44c3-847a-0922063ac958' User entered '11 Aug 2020 21:05'	System	12 Aug 2020 04:05:39
	System	12 Aug 2020 04:05:39

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 3'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:50

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:40:17', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '5c54456d-9ed8-4fe0-a783-d11f08edeb60' User entered 'Yes (Y)'	System	12 Aug 2020 23:40:43
	System	12 Aug 2020 23:40:43

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:40:25', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '5c54456d-9ed8-4fe0-a783-d11f08edeb60' User entered '98.5'	System	12 Aug 2020 23:40:43
	System	12 Aug 2020 23:40:43

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:40:32', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '5c54456d-9ed8-4fe0-a783-d11f08edeb60' User entered 'No (N)'	System	12 Aug 2020 23:40:43
	System	12 Aug 2020 23:40:43

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:40:40', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '5c54456d-9ed8-4fe0-a783-d11f08edeb60' User entered '12 Aug 2020 16:40'	System	12 Aug 2020 23:40:43
	System	12 Aug 2020 23:40:43

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 4'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:50

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:03:04', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '2b3d0886-e7a7-4741-9a78-b0d19b26ffff' User entered 'Yes (Y)'	System	14 Aug 2020 05:03:27
	System	14 Aug 2020 05:03:27

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:03:12', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '2b3d0886-e7a7-4741-9a78-b0d19b26ffff' User entered '98.6'	System	14 Aug 2020 05:03:27
	System	14 Aug 2020 05:03:27

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:03:19', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '2b3d0886-e7a7-4741-9a78-b0d19b26ffff' User entered 'No (N)'	System	14 Aug 2020 05:03:27
	System	14 Aug 2020 05:03:27

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:03:25', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '2b3d0886-e7a7-4741-9a78-b0d19b26ffff' User entered '13 Aug 2020 22:03'	System	14 Aug 2020 05:03:27
	System	14 Aug 2020 05:03:27

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 5'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:50

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:40:01', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '0e714022-b6dc-43ec-b7db-72b9e362367e' User entered 'Yes (Y)'	System	14 Aug 2020 23:40:19
	System	14 Aug 2020 23:40:19

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:40:08', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '0e714022-b6dc-43ec-b7db-72b9e362367e' User entered '98.6'	System	14 Aug 2020 23:40:19
	System	14 Aug 2020 23:40:19

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:40:14', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '0e714022-b6dc-43ec-b7db-72b9e362367e'	System	14 Aug 2020 23:40:19
User entered 'No (N)'	System	14 Aug 2020 23:40:19

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:40:18', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '0e714022-b6dc-43ec-b7db-72b9e362367e' User entered '14 Aug 2020 16:40'	System	14 Aug 2020 23:40:19
	System	14 Aug 2020 23:40:19

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 6'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:50

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:41:40', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'd035211a-2e39-4f30-966d-86be676331b0' User entered 'Yes (Y)'	System	15 Aug 2020 22:42:03
	System	15 Aug 2020 22:42:03

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:41:47', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'd035211a-2e39-4f30-966d-86be676331b0' User entered '98.2'	System	15 Aug 2020 22:42:03
	System	15 Aug 2020 22:42:03

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:41:53', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'd035211a-2e39-4f30-966d-86be676331b0'	System	15 Aug 2020 22:42:03
User entered 'No (N)'	System	15 Aug 2020 22:42:03

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:42:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'd035211a-2e39-4f30-966d-86be676331b0' User entered '15 Aug 2020 15:42'	System	15 Aug 2020 22:42:03
	System	15 Aug 2020 22:42:03

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 7'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:50

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:12:22', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'f968190c-fc9a-4087-ad4c-fa571d2ef816' User entered 'Yes (Y)'	System	17 Aug 2020 03:12:43
	System	17 Aug 2020 03:12:43

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:12:29', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'f968190c-fc9a-4087-ad4c-fa571d2ef816' User entered '98.7'	System	17 Aug 2020 03:12:43
	System	17 Aug 2020 03:12:43

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:12:35', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'f968190c-fc9a-4087-ad4c-fa571d2ef816'	System	17 Aug 2020 03:12:43
User entered 'No (N)'	System	17 Aug 2020 03:12:43

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:12:40', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'f968190c-fc9a-4087-ad4c-fa571d2ef816'	System	17 Aug 2020 03:12:43
User entered '16 Aug 2020 20:12'	System	17 Aug 2020 03:12:43

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:26:21', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'b6969bec-fde4-4651-b804-e5e1c72ad53e' User entered 'None (1)'	System	10 Aug 2020 22:27:50
	System	10 Aug 2020 22:27:50

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:27:11', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'b6969bec-fde4-4651-b804-e5e1c72ad53e' User entered 'No (N)'	System	10 Aug 2020 22:27:50
	System	10 Aug 2020 22:27:50

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:27:17', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'b6969bec-fde4-4651-b804-e5e1c72ad53e' User entered 'No (N)'	System	10 Aug 2020 22:27:50
	System	10 Aug 2020 22:27:50

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:27:27', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'b6969bec-fde4-4651-b804-e5e1c72ad53e' User entered 'None (1)'	System	10 Aug 2020 22:27:50
	System	10 Aug 2020 22:27:50

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:27:47', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'b6969bec-fde4-4651-b804-e5e1c72ad53e' User entered '10 Aug 2020 15:27'	System	10 Aug 2020 22:27:50
	System	10 Aug 2020 22:27:50

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '10 Aug 2020 15:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '10 Aug 2020 17:30'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:32:29', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '64dc5735-c816-4ffd-a121-d79974ef1fdd'	System	11 Aug 2020 02:33:38
User entered 'None (1)'	System	11 Aug 2020 02:33:38

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:32:47', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '64dc5735-c816-4ffd-a121-d79974ef1fdd'	System	11 Aug 2020 02:33:38
User entered 'No (N)'	System	11 Aug 2020 02:33:38

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:32:58', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '64dc5735-c816-4ffd-a121-d79974ef1fdd'	System	11 Aug 2020 02:33:38
User entered 'No (N)'	System	11 Aug 2020 02:33:38

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:33:11', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '64dc5735-c816-4ffd-a121-d79974ef1fdd'	System	11 Aug 2020 02:33:38
User entered 'None (1)'	System	11 Aug 2020 02:33:38

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:33:32', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '64dc5735-c816-4ffd-a121-d79974ef1fdd'	System	11 Aug 2020 02:33:38
User entered '10 Aug 2020 19:33'	System	11 Aug 2020 02:33:38

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '10 Aug 2020 18:25'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 2'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:06:05', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '68d30a5e-7212-432d-8970-e9961a4111e5'	System	12 Aug 2020 04:06:47
User entered 'None (1)'	System	12 Aug 2020 04:06:47

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:06:11', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '68d30a5e-7212-432d-8970-e9961a4111e5'	System	12 Aug 2020 04:06:47
User entered 'No (N)'	System	12 Aug 2020 04:06:47

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:06:22', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '68d30a5e-7212-432d-8970-e9961a4111e5' User entered 'No (N)'	System	12 Aug 2020 04:06:47
	System	12 Aug 2020 04:06:47

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:06:37', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '68d30a5e-7212-432d-8970-e9961a4111e5' User entered 'None (1)'	System	12 Aug 2020 04:06:47
	System	12 Aug 2020 04:06:47

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:06:44', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '68d30a5e-7212-432d-8970-e9961a4111e5' User entered '11 Aug 2020 21:06'	System	12 Aug 2020 04:06:47
	System	12 Aug 2020 04:06:47

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 3'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:41:13', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '025c4a85-a87e-439b-8591-38f73dfe20ee'	System	12 Aug 2020 23:41:45
User entered 'None (1)'	System	12 Aug 2020 23:41:45

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:41:18', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '025c4a85-a87e-439b-8591-38f73dfe20ee' User entered 'No (N)'	System	12 Aug 2020 23:41:45
	System	12 Aug 2020 23:41:45

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:41:23', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '025c4a85-a87e-439b-8591-38f73dfe20ee'	System	12 Aug 2020 23:41:45
User entered 'No (N)'	System	12 Aug 2020 23:41:45

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:41:32', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '025c4a85-a87e-439b-8591-38f73dfe20ee'	System	12 Aug 2020 23:41:45
User entered 'None (1)'	System	12 Aug 2020 23:41:45

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:41:41', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '025c4a85-a87e-439b-8591-38f73dfe20ee' User entered '12 Aug 2020 16:41'	System	12 Aug 2020 23:41:45
	System	12 Aug 2020 23:41:45

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 4'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:03:39', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '98d4235b-091a-4706-86f6-d3865f84abcf' User entered 'None (1)'	System	14 Aug 2020 05:04:13
	System	14 Aug 2020 05:04:13

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:03:45', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '98d4235b-091a-4706-86f6-d3865f84abcf' User entered 'No (N)'	System	14 Aug 2020 05:04:13
	System	14 Aug 2020 05:04:13

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:03:57', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '98d4235b-091a-4706-86f6-d3865f84abcf' User entered 'No (N)'	System	14 Aug 2020 05:04:13
	System	14 Aug 2020 05:04:13

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:04:06', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '98d4235b-091a-4706-86f6-d3865f84abcf' User entered 'None (1)'	System	14 Aug 2020 05:04:13
	System	14 Aug 2020 05:04:13

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:04:11', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '98d4235b-091a-4706-86f6-d3865f84abcf' User entered '13 Aug 2020 22:04'	System	14 Aug 2020 05:04:13
	System	14 Aug 2020 05:04:13

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 5'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:40:27', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '5765d230-1435-4b21-ae0a-e7807c16b4cf' User entered 'None (1)'	System	14 Aug 2020 23:40:55
	System	14 Aug 2020 23:40:55

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:40:33', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '5765d230-1435-4b21-ae0a-e7807c16b4cf' User entered 'No (N)'	System	14 Aug 2020 23:40:55
	System	14 Aug 2020 23:40:55

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:40:39', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '5765d230-1435-4b21-ae0a-e7807c16b4cf' User entered 'No (N)'	System	14 Aug 2020 23:40:55
	System	14 Aug 2020 23:40:55

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:40:47', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '5765d230-1435-4b21-ae0a-e7807c16b4cf' User entered 'None (1)'	System	14 Aug 2020 23:40:55
	System	14 Aug 2020 23:40:55

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:40:52', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '5765d230-1435-4b21-ae0a-e7807c16b4cf' User entered '14 Aug 2020 16:40'	System	14 Aug 2020 23:40:55
	System	14 Aug 2020 23:40:55

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 6'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:42:23', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8f52f701-30d9-4146-97c3-06be5b9f0a8c' User entered 'None (1)'	System	15 Aug 2020 22:42:46
	System	15 Aug 2020 22:42:46

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:42:28', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8f52f701-30d9-4146-97c3-06be5b9f0a8c'	System	15 Aug 2020 22:42:46
User entered 'No (N)'	System	15 Aug 2020 22:42:46

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:42:35', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8f52f701-30d9-4146-97c3-06be5b9f0a8c'	System	15 Aug 2020 22:42:46
User entered 'No (N)'	System	15 Aug 2020 22:42:46

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:42:38', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8f52f701-30d9-4146-97c3-06be5b9f0a8c'	System	15 Aug 2020 22:42:46
User entered 'None (1)'	System	15 Aug 2020 22:42:46

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:42:45', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8f52f701-30d9-4146-97c3-06be5b9f0a8c' User entered '15 Aug 2020 15:42'	System	15 Aug 2020 22:42:46
	System	15 Aug 2020 22:42:46

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 7'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:12:50', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ae8c8557-4b28-48fe-a77f-174454922898'	System	17 Aug 2020 03:13:22
User entered 'None (1)'	System	17 Aug 2020 03:13:22

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:13:02', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ae8c8557-4b28-48fe-a77f-174454922898' User entered 'No (N)'	System	17 Aug 2020 03:13:22
	System	17 Aug 2020 03:13:22

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:13:07', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ae8c8557-4b28-48fe-a77f-174454922898' User entered 'No (N)'	System	17 Aug 2020 03:13:22
	System	17 Aug 2020 03:13:22

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:13:14', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ae8c8557-4b28-48fe-a77f-174454922898' User entered 'None (1)'	System	17 Aug 2020 03:13:22
	System	17 Aug 2020 03:13:22

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:13:20', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ae8c8557-4b28-48fe-a77f-174454922898' User entered '16 Aug 2020 20:13'	System	17 Aug 2020 03:13:22
	System	17 Aug 2020 03:13:22

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:28:08', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '85db5557-778e-4d1a-a1dd-4e8f357466a7' User entered 'None (0)'	System	10 Aug 2020 22:29:04
	System	10 Aug 2020 22:29:04

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:28:19', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '85db5557-778e-4d1a-a1dd-4e8f357466a7' User entered 'None (0)'	System	10 Aug 2020 22:29:04
	System	10 Aug 2020 22:29:04

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:28:23', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '85db5557-778e-4d1a-a1dd-4e8f357466a7' User entered 'None (0)'	System	10 Aug 2020 22:29:04
	System	10 Aug 2020 22:29:04

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:28:29', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '85db5557-778e-4d1a-a1dd-4e8f357466a7' User entered 'None (0)'	System	10 Aug 2020 22:29:04
	System	10 Aug 2020 22:29:04

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:28:38', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '85db5557-778e-4d1a-a1dd-4e8f357466a7' User entered 'None (0)'	System	10 Aug 2020 22:29:04
	System	10 Aug 2020 22:29:04

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:28:41', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '85db5557-778e-4d1a-a1dd-4e8f357466a7' User entered 'None (0)'	System	10 Aug 2020 22:29:04
	System	10 Aug 2020 22:29:04

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:28:52', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '85db5557-778e-4d1a-a1dd-4e8f357466a7' User entered 'No (N)'	System	10 Aug 2020 22:29:04
	System	10 Aug 2020 22:29:04

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T15:29:02', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '85db5557-778e-4d1a-a1dd-4e8f357466a7' User entered '10 Aug 2020 15:29'	System	10 Aug 2020 22:29:04
	System	10 Aug 2020 22:29:04

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '10 Aug 2020 15:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '10 Aug 2020 17:30'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:33:46', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '4ee69071-8a59-476d-b213-c21fd86b82eb' User entered 'None (0)'	System	11 Aug 2020 02:34:42
	System	11 Aug 2020 02:34:42

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:33:53', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '4ee69071-8a59-476d-b213-c21fd86b82eb' User entered 'None (0)'	System	11 Aug 2020 02:34:42
	System	11 Aug 2020 02:34:42

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:34:07', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '4ee69071-8a59-476d-b213-c21fd86b82eb' User entered 'None (0)'	System	11 Aug 2020 02:34:42
	System	11 Aug 2020 02:34:42

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:34:13', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '4ee69071-8a59-476d-b213-c21fd86b82eb' User entered 'None (0)'	System	11 Aug 2020 02:34:42
	System	11 Aug 2020 02:34:42

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:34:17', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '4ee69071-8a59-476d-b213-c21fd86b82eb' User entered 'None (0)'	System	11 Aug 2020 02:34:42
	System	11 Aug 2020 02:34:42

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:34:21', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '4ee69071-8a59-476d-b213-c21fd86b82eb' User entered 'None (0)'	System	11 Aug 2020 02:34:42
	System	11 Aug 2020 02:34:42

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:34:32', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '4ee69071-8a59-476d-b213-c21fd86b82eb' User entered 'No (N)'	System	11 Aug 2020 02:34:42
	System	11 Aug 2020 02:34:42

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-10T19:34:39', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '4ee69071-8a59-476d-b213-c21fd86b82eb' User entered '10 Aug 2020 19:34'	System	11 Aug 2020 02:34:42
	System	11 Aug 2020 02:34:42

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '10 Aug 2020 18:25'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 2'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:06:56', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'de406ae1-3e00-414c-9a82-9f5240946cb1' User entered 'None (0)'	System	12 Aug 2020 04:07:41
	System	12 Aug 2020 04:07:41

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:07:02', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'de406ae1-3e00-414c-9a82-9f5240946cb1' User entered 'None (0)'	System	12 Aug 2020 04:07:41
	System	12 Aug 2020 04:07:41

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:07:13', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'de406ae1-3e00-414c-9a82-9f5240946cb1' User entered 'None (0)'	System	12 Aug 2020 04:07:41
	System	12 Aug 2020 04:07:41

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:07:18', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'de406ae1-3e00-414c-9a82-9f5240946cb1' User entered 'None (0)'	System	12 Aug 2020 04:07:41
	System	12 Aug 2020 04:07:41

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:07:21', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'de406ae1-3e00-414c-9a82-9f5240946cb1' User entered 'None (0)'	System	12 Aug 2020 04:07:41
	System	12 Aug 2020 04:07:41

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:07:25', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'de406ae1-3e00-414c-9a82-9f5240946cb1' User entered 'None (0)'	System	12 Aug 2020 04:07:41
	System	12 Aug 2020 04:07:41

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:07:32', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'de406ae1-3e00-414c-9a82-9f5240946cb1' User entered 'No (N)'	System	12 Aug 2020 04:07:41
	System	12 Aug 2020 04:07:41

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-11T21:07:39', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'de406ae1-3e00-414c-9a82-9f5240946cb1' User entered '11 Aug 2020 21:07'	System	12 Aug 2020 04:07:41
	System	12 Aug 2020 04:07:41

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 3'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:41:58', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'b381b6cc-e4f1-4028-b2ab-0bc40a260cd9' User entered 'None (0)'	System	12 Aug 2020 23:42:29
	System	12 Aug 2020 23:42:29

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:42:01', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'b381b6cc-e4f1-4028-b2ab-0bc40a260cd9' User entered 'None (0)'	System	12 Aug 2020 23:42:29
	System	12 Aug 2020 23:42:29

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:42:04', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'b381b6cc-e4f1-4028-b2ab-0bc40a260cd9' User entered 'None (0)'	System	12 Aug 2020 23:42:29
	System	12 Aug 2020 23:42:29

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:42:08', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'b381b6cc-e4f1-4028-b2ab-0bc40a260cd9' User entered 'None (0)'	System	12 Aug 2020 23:42:29
	System	12 Aug 2020 23:42:29

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:42:12', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'b381b6cc-e4f1-4028-b2ab-0bc40a260cd9' User entered 'None (0)'	System	12 Aug 2020 23:42:29
	System	12 Aug 2020 23:42:29

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:42:14', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'b381b6cc-e4f1-4028-b2ab-0bc40a260cd9' User entered 'None (0)'	System	12 Aug 2020 23:42:29
	System	12 Aug 2020 23:42:29

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:42:21', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'b381b6cc-e4f1-4028-b2ab-0bc40a260cd9' User entered 'No (N)'	System	12 Aug 2020 23:42:29
	System	12 Aug 2020 23:42:29

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-12T16:42:27', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'b381b6cc-e4f1-4028-b2ab-0bc40a260cd9' User entered '12 Aug 2020 16:42'	System	12 Aug 2020 23:42:29
	System	12 Aug 2020 23:42:29

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 4'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:04:21', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '53aa8ab9-23d5-4cb3-a59b-9ba55bdc160a' User entered 'None (0)'	System	14 Aug 2020 05:05:06
	System	14 Aug 2020 05:05:06

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:04:24', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '53aa8ab9-23d5-4cb3-a59b-9ba55bdc160a' User entered 'None (0)'	System	14 Aug 2020 05:05:06
	System	14 Aug 2020 05:05:06

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:04:30', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '53aa8ab9-23d5-4cb3-a59b-9ba55bdc160a' User entered 'None (0)'	System	14 Aug 2020 05:05:06
	System	14 Aug 2020 05:05:06

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:04:37', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '53aa8ab9-23d5-4cb3-a59b-9ba55bdc160a' User entered 'None (0)'	System	14 Aug 2020 05:05:06
	System	14 Aug 2020 05:05:06

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:04:51', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '53aa8ab9-23d5-4cb3-a59b-9ba55bdc160a' User entered 'None (0)'	System	14 Aug 2020 05:05:06
	System	14 Aug 2020 05:05:06

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:04:54', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '53aa8ab9-23d5-4cb3-a59b-9ba55bdc160a' User entered 'None (0)'	System	14 Aug 2020 05:05:06
	System	14 Aug 2020 05:05:06

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:05:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '53aa8ab9-23d5-4cb3-a59b-9ba55bdc160a' User entered 'No (N)'	System	14 Aug 2020 05:05:06
	System	14 Aug 2020 05:05:06

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-13T22:05:04', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '53aa8ab9-23d5-4cb3-a59b-9ba55bdc160a' User entered '13 Aug 2020 22:05'	System	14 Aug 2020 05:05:06
	System	14 Aug 2020 05:05:06

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 5'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:41:02', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c50ac598-28d5-4451-89b4-acfe5073a0e4' User entered 'None (0)'	System	14 Aug 2020 23:41:28
	System	14 Aug 2020 23:41:28

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:41:04', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c50ac598-28d5-4451-89b4-acfe5073a0e4' User entered 'None (0)'	System	14 Aug 2020 23:41:28
	System	14 Aug 2020 23:41:28

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:41:07', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c50ac598-28d5-4451-89b4-acfe5073a0e4' User entered 'None (0)'	System	14 Aug 2020 23:41:28
	System	14 Aug 2020 23:41:28

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:41:11', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c50ac598-28d5-4451-89b4-acfe5073a0e4' User entered 'None (0)'	System	14 Aug 2020 23:41:28
	System	14 Aug 2020 23:41:28

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:41:14', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c50ac598-28d5-4451-89b4-acfe5073a0e4' User entered 'None (0)'	System	14 Aug 2020 23:41:28
	System	14 Aug 2020 23:41:28

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:41:17', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c50ac598-28d5-4451-89b4-acfe5073a0e4' User entered 'None (0)'	System	14 Aug 2020 23:41:28
	System	14 Aug 2020 23:41:28

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:41:21', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c50ac598-28d5-4451-89b4-acfe5073a0e4' User entered 'No (N)'	System	14 Aug 2020 23:41:28
	System	14 Aug 2020 23:41:28

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-14T16:41:26', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c50ac598-28d5-4451-89b4-acfe5073a0e4' User entered '14 Aug 2020 16:41'	System	14 Aug 2020 23:41:28
	System	14 Aug 2020 23:41:28

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 6'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:42:52', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '4c844c9a-03d2-48d7-b444-6c9e45f30d39' User entered 'None (0)'	System	15 Aug 2020 22:43:23
	System	15 Aug 2020 22:43:23

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:42:54', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '4c844c9a-03d2-48d7-b444-6c9e45f30d39' User entered 'None (0)'	System	15 Aug 2020 22:43:23
	System	15 Aug 2020 22:43:23

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:42:57', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '4c844c9a-03d2-48d7-b444-6c9e45f30d39' User entered 'None (0)'	System	15 Aug 2020 22:43:23
	System	15 Aug 2020 22:43:23

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:43:01', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '4c844c9a-03d2-48d7-b444-6c9e45f30d39' User entered 'None (0)'	System	15 Aug 2020 22:43:23
	System	15 Aug 2020 22:43:23

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:43:04', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '4c844c9a-03d2-48d7-b444-6c9e45f30d39' User entered 'None (0)'	System	15 Aug 2020 22:43:23
	System	15 Aug 2020 22:43:23

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:43:06', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '4c844c9a-03d2-48d7-b444-6c9e45f30d39' User entered 'None (0)'	System	15 Aug 2020 22:43:23
	System	15 Aug 2020 22:43:23

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:43:16', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '4c844c9a-03d2-48d7-b444-6c9e45f30d39'	System	15 Aug 2020 22:43:23
User entered 'No (N)'	System	15 Aug 2020 22:43:23

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-15T15:43:21', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '4c844c9a-03d2-48d7-b444-6c9e45f30d39' User entered '15 Aug 2020 15:43'	System	15 Aug 2020 22:43:23
	System	15 Aug 2020 22:43:23

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 7'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:13:26', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'bfe3b57d-4fef-4f4c-887b-5e20edff720b' User entered 'None (0)'	System	17 Aug 2020 03:14:13
	System	17 Aug 2020 03:14:13

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:13:29', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'bfe3b57d-4fef-4f4c-887b-5e20edff720b' User entered 'None (0)'	System	17 Aug 2020 03:14:13
	System	17 Aug 2020 03:14:13

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:13:44', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'bfe3b57d-4fef-4f4c-887b-5e20edff720b' User entered 'None (0)'	System	17 Aug 2020 03:14:13
	System	17 Aug 2020 03:14:13

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:13:49', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'bfe3b57d-4fef-4f4c-887b-5e20edff720b' User entered 'None (0)'	System	17 Aug 2020 03:14:13
	System	17 Aug 2020 03:14:13

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:13:52', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'bfe3b57d-4fef-4f4c-887b-5e20edff720b' User entered 'None (0)'	System	17 Aug 2020 03:14:13
	System	17 Aug 2020 03:14:13

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:13:55', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'bfe3b57d-4fef-4f4c-887b-5e20edff720b' User entered 'None (0)'	System	17 Aug 2020 03:14:13
	System	17 Aug 2020 03:14:13

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:14:04', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'bfe3b57d-4fef-4f4c-887b-5e20edff720b'	System	17 Aug 2020 03:14:13
User entered 'No (N)'	System	17 Aug 2020 03:14:13

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-08-16T20:14:10', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'bfe3b57d-4fef-4f4c-887b-5e20edff720b' User entered '16 Aug 2020 20:14'	System	17 Aug 2020 03:14:13
	System	17 Aug 2020 03:14:13

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 21:47:48

US3162090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:04:40

US3162090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '17 Aug 2020'	Jared Bradshaw (b) (4)	18 Aug 2020 04:04:40
	(b) (4)	

US3162090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:04:40

US3162090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:04:40

US3162090

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:05:30

US3162090

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'I'	System	18 Aug 2020 04:05:30

US3162090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 15:22:36

US3162090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '24 Aug 2020'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:22:36
	(b) (4)	

US3162090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 15:22:36

US3162090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 15:22:36

US3162090

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 15:22:42

US3162090

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'I'	System	28 Aug 2020 15:22:42

US3162090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	02 Sep 2020 03:40:50

US3162090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '31 Aug 2020'	Jared Bradshaw (b) (4)	02 Sep 2020 03:40:50
	(b) (4)	

US3162090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	02 Sep 2020 03:40:50

US3162090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	02 Sep 2020 03:40:50

US3162090

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	02 Sep 2020 03:40:55

US3162090

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'I'	System	02 Sep 2020 03:40:55

US3162090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:18:27

US3162090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '8 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:18:27

US3162090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[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 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:18:27

US3162090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'VISIT2'	System	09 Sep 2020 03:18:27

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User accepted default value 'Pre-Dose (PREDOSE)'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '8 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '14:40'	Jared Bradshaw (b) (4)	09 Sep 2020 03:19:32
	(b) (4)	

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered '8 Sep 2020 14:40'	System	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '98.9' F	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '76'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'bpm'	System	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '14'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'breaths/min'	System	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '117'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'mmHg'	System	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '71'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'mmHg'	System	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User accepted default value 'Post-Dose (POSTDOSE)'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '8 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '17:00'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered '8 Sep 2020 17:00'	System	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '97.5' F	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '65'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'bpm'	System	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '12'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'breaths/min'	System	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '114'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'mmHg'	System	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '72'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'mmHg'	System	09 Sep 2020 03:19:32

US3162090

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:54

US3162090

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:19:54

US3162090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jourdan Manfred (b) (4) (b) (4)	08 Sep 2020 23:27:42

US3162090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered empty.	Jourdan Manfred (b) (4)	08 Sep 2020 23:27:42
	(b) (4)	

US3162090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

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 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jourdan Manfred (b) (4) (b) (4)	08 Sep 2020 23:27:42

US3162090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 23:27:42

US3162090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '8 Sep 2020'	Jourdan Manfred (b) (4)	08 Sep 2020 23:27:42
	(b) (4)	

US3162090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '16:23'	Jourdan Manfred (b) (4) (b) (4)	08 Sep 2020 23:27:42

US3162090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered '8 Sep 2020 16:23'	System	08 Sep 2020 23:27:42

US3162090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Left Arm (LEFT ARM)'	Jourdan Manfred (b) (4) (b) (4)	08 Sep 2020 23:27:42

US3162090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'ONCE'	System	08 Sep 2020 23:27:42

US3162090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 23:27:42

US3162090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:20:10

US3162090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '8 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:20:10

US3162090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '15:14'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:20:10

US3162090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered '8 Sep 2020 15:14'	System	09 Sep 2020 03:20:10

US3162090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '8 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:20:19

US3162090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jared Bradshaw (b) (4)	09 Sep 2020 03:20:19

US3162090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:20:19

US3162090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:50

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '15:18'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:20:19

US3162090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered '8 Sep 2020 15:18'	System	09 Sep 2020 03:20:19

US3162090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jared Bradshaw (b) (4)	09 Sep 2020 03:20:19

US3162090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:20:19

US3162090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:20:19

US3162090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered empty.	System	09 Sep 2020 03:20:19

US3162090

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 03:20:25

US3162090

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'I'	System	09 Sep 2020 03:20:25

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:03:01', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '70372282-6744-48ea-b30b-dc44648b6775'	System	09 Sep 2020 00:03:39
User entered 'Yes (Y)'	System	09 Sep 2020 00:03:39

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:03:14', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '70372282-6744-48ea-b30b-dc44648b6775' User entered '97.5'	System	09 Sep 2020 00:03:39
	System	09 Sep 2020 00:03:39

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:03:22', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '70372282-6744-48ea-b30b-dc44648b6775'	System	09 Sep 2020 00:03:39
User entered 'No (N)'	System	09 Sep 2020 00:03:39

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:03:37', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '70372282-6744-48ea-b30b-dc44648b6775' User entered '08 Sep 2020 17:03'	System	09 Sep 2020 00:03:39
	System	09 Sep 2020 00:03:39

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '08 Sep 2020 16:43'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '08 Sep 2020 19:13'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:01:20', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'f853b745-3790-4a53-9a0c-69e90ed222df' User entered 'Yes (Y)'	System	09 Sep 2020 05:02:05
	System	09 Sep 2020 05:02:05

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:01:46', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'f853b745-3790-4a53-9a0c-69e90ed222df' User entered '97.3'	System	09 Sep 2020 05:02:05
	System	09 Sep 2020 05:02:05

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:01:52', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'f853b745-3790-4a53-9a0c-69e90ed222df' User entered 'No (N)'	System	09 Sep 2020 05:02:05
	System	09 Sep 2020 05:02:05

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:02:01', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'f853b745-3790-4a53-9a0c-69e90ed222df' User entered '08 Sep 2020 22:02'	System	09 Sep 2020 05:02:05
	System	09 Sep 2020 05:02:05

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '08 Sep 2020 20:08'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 2'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:50

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T09:58:53', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '69c9d52f-e9db-4a51-9955-a9b9c0dba63e' User entered 'Yes (Y)'	System	10 Sep 2020 16:59:22
	System	10 Sep 2020 16:59:22

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T09:59:06', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '69c9d52f-e9db-4a51-9955-a9b9c0dba63e' User entered '98.2'	System	10 Sep 2020 16:59:22
	System	10 Sep 2020 16:59:22

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T09:59:10', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '69c9d52f-e9db-4a51-9955-a9b9c0dba63e' User entered 'No (N)'	System	10 Sep 2020 16:59:22
	System	10 Sep 2020 16:59:22

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T09:59:17', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '69c9d52f-e9db-4a51-9955-a9b9c0dba63e' User entered '10 Sep 2020 09:59'	System	10 Sep 2020 16:59:22
	System	10 Sep 2020 16:59:22

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 3'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:50

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:11:55', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3ad1c8da-a63c-48cd-8fb9-c3fb436deaf9' User entered 'Yes (Y)'	System	11 Sep 2020 05:12:17
	System	11 Sep 2020 05:12:17

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:12:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3ad1c8da-a63c-48cd-8fb9-c3fb436deaf9' User entered '97.3'	System	11 Sep 2020 05:12:17
	System	11 Sep 2020 05:12:17

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:12:07', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3ad1c8da-a63c-48cd-8fb9-c3fb436deaf9' User entered 'No (N)'	System	11 Sep 2020 05:12:17
	System	11 Sep 2020 05:12:17

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:12:14', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3ad1c8da-a63c-48cd-8fb9-c3fb436deaf9' User entered '10 Sep 2020 22:12'	System	11 Sep 2020 05:12:17
	System	11 Sep 2020 05:12:17

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 4'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:50

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:13:26', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '70a0e5a9-db6b-4181-8b89-6878b875b801' User entered 'Yes (Y)'	System	12 Sep 2020 05:13:50
	System	12 Sep 2020 05:13:50

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:13:31', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '70a0e5a9-db6b-4181-8b89-6878b875b801' User entered '97.7'	System	12 Sep 2020 05:13:50
	System	12 Sep 2020 05:13:50

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:13:39', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '70a0e5a9-db6b-4181-8b89-6878b875b801'	System	12 Sep 2020 05:13:50
User entered 'No (N)'	System	12 Sep 2020 05:13:50

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:13:44', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '70a0e5a9-db6b-4181-8b89-6878b875b801'	System	12 Sep 2020 05:13:50
User entered '11 Sep 2020 22:13'	System	12 Sep 2020 05:13:50

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 5'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:50

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:57:10', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '52fa6769-61a9-4694-af6b-a1a8b4284c83' User entered 'Yes (Y)'	System	13 Sep 2020 03:57:36
	System	13 Sep 2020 03:57:36

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:57:21', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '52fa6769-61a9-4694-af6b-a1a8b4284c83' User entered '98.2'	System	13 Sep 2020 03:57:36
	System	13 Sep 2020 03:57:36

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:57:28', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '52fa6769-61a9-4694-af6b-a1a8b4284c83'	System	13 Sep 2020 03:57:36
User entered 'No (N)'	System	13 Sep 2020 03:57:36

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:57:35', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '52fa6769-61a9-4694-af6b-a1a8b4284c83' User entered '12 Sep 2020 20:57'	System	13 Sep 2020 03:57:36
	System	13 Sep 2020 03:57:36

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 6'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:20:51', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'a0a131bc-74f6-4481-a290-f4c83aed01b5' User entered 'Yes (Y)'	System	14 Sep 2020 05:21:08
	System	14 Sep 2020 05:21:08

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:20:57', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'a0a131bc-74f6-4481-a290-f4c83aed01b5' User entered '97.7'	System	14 Sep 2020 05:21:08
	System	14 Sep 2020 05:21:08

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:21:01', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'a0a131bc-74f6-4481-a290-f4c83aed01b5'	System	14 Sep 2020 05:21:08
User entered 'No (N)'	System	14 Sep 2020 05:21:08

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:21:05', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'a0a131bc-74f6-4481-a290-f4c83aed01b5' User entered '13 Sep 2020 22:21'	System	14 Sep 2020 05:21:08
	System	14 Sep 2020 05:21:08

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 7'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:50

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:02:03', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3c5eb81a-5730-4daf-a65c-a71c5303fa36' User entered 'Yes (Y)'	System	15 Sep 2020 03:02:19
	System	15 Sep 2020 03:02:19

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:02:08', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3c5eb81a-5730-4daf-a65c-a71c5303fa36' User entered '98.3'	System	15 Sep 2020 03:02:19
	System	15 Sep 2020 03:02:19

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:02:13', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3c5eb81a-5730-4daf-a65c-a71c5303fa36'	System	15 Sep 2020 03:02:19
User entered 'No (N)'	System	15 Sep 2020 03:02:19

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:02:18', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3c5eb81a-5730-4daf-a65c-a71c5303fa36' User entered '14 Sep 2020 20:02'	System	15 Sep 2020 03:02:19
	System	15 Sep 2020 03:02:19

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:04:35', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'e9f04beb-c32a-4057-9a51-99ded52a4b2d'	System	09 Sep 2020 00:05:48
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 00:05:48

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:04:58', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'e9f04beb-c32a-4057-9a51-99ded52a4b2d' User entered 'No (N)'	System	09 Sep 2020 00:05:48
	System	09 Sep 2020 00:05:48

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:05:25', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'e9f04beb-c32a-4057-9a51-99ded52a4b2d' User entered 'No (N)'	System	09 Sep 2020 00:05:48
	System	09 Sep 2020 00:05:48

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:05:34', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'e9f04beb-c32a-4057-9a51-99ded52a4b2d' User entered 'None (1)'	System	09 Sep 2020 00:05:48
	System	09 Sep 2020 00:05:48

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:05:46', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'e9f04beb-c32a-4057-9a51-99ded52a4b2d' User entered '08 Sep 2020 17:05'	System	09 Sep 2020 00:05:48
	System	09 Sep 2020 00:05:48

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '08 Sep 2020 16:43'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '08 Sep 2020 19:13'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:02:46', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '37cab116-0e98-40e7-b2e9-bed0969bfd4a' User entered 'None (1)'	System	09 Sep 2020 05:03:22
	System	09 Sep 2020 05:03:22

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:02:54', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '37cab116-0e98-40e7-b2e9-bed0969bfd4a' User entered 'No (N)'	System	09 Sep 2020 05:03:22
	System	09 Sep 2020 05:03:22

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:02:58', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '37cab116-0e98-40e7-b2e9-bed0969bfd4a' User entered 'No (N)'	System	09 Sep 2020 05:03:22
	System	09 Sep 2020 05:03:22

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:03:08', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '37cab116-0e98-40e7-b2e9-bed0969bfd4a' User entered 'None (1)'	System	09 Sep 2020 05:03:22
	System	09 Sep 2020 05:03:22

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:03:19', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '37cab116-0e98-40e7-b2e9-bed0969bfd4a' User entered '08 Sep 2020 22:03'	System	09 Sep 2020 05:03:22
	System	09 Sep 2020 05:03:22

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '08 Sep 2020 20:08'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 2'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T09:59:29', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3a7dfb14-601c-4283-9251-f0b75d380129'	System	10 Sep 2020 17:00:14
User entered 'None (1)'	System	10 Sep 2020 17:00:14

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T09:59:52', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3a7dfb14-601c-4283-9251-f0b75d380129'	System	10 Sep 2020 17:00:14
User entered 'No (N)'	System	10 Sep 2020 17:00:14

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T09:59:58', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3a7dfb14-601c-4283-9251-f0b75d380129' User entered 'No (N)'	System	10 Sep 2020 17:00:14
	System	10 Sep 2020 17:00:14

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T10:00:08', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3a7dfb14-601c-4283-9251-f0b75d380129' User entered 'None (1)'	System	10 Sep 2020 17:00:14
	System	10 Sep 2020 17:00:14

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T10:00:12', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3a7dfb14-601c-4283-9251-f0b75d380129'	System	10 Sep 2020 17:00:14
User entered '10 Sep 2020 10:00'	System	10 Sep 2020 17:00:14

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 3'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:12:28', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '68ecf064-9fd9-4d8a-98b2-dd8e2fbd3788' User entered 'None (1)'	System	11 Sep 2020 05:12:57
	System	11 Sep 2020 05:12:57

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:12:33', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '68ecf064-9fd9-4d8a-98b2-dd8e2fbd3788'	System	11 Sep 2020 05:12:57
User entered 'No (N)'	System	11 Sep 2020 05:12:57

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:12:43', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '68ecf064-9fd9-4d8a-98b2-dd8e2fbd3788'	System	11 Sep 2020 05:12:57
User entered 'No (N)'	System	11 Sep 2020 05:12:57

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:12:51', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '68ecf064-9fd9-4d8a-98b2-dd8e2fbd3788'	System	11 Sep 2020 05:12:57
User entered 'None (1)'	System	11 Sep 2020 05:12:57

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:12:55', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '68ecf064-9fd9-4d8a-98b2-dd8e2fbd3788' User entered '10 Sep 2020 22:12'	System	11 Sep 2020 05:12:57
	System	11 Sep 2020 05:12:57

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 4'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:13:53', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '7773a530-02a9-42ef-b2f1-6fd2727b59fe' User entered 'None (1)'	System	12 Sep 2020 05:14:25
	System	12 Sep 2020 05:14:25

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:13:56', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '7773a530-02a9-42ef-b2f1-6fd2727b59fe' User entered 'No (N)'	System	12 Sep 2020 05:14:25
	System	12 Sep 2020 05:14:25

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:14:02', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '7773a530-02a9-42ef-b2f1-6fd2727b59fe'	System	12 Sep 2020 05:14:25
User entered 'No (N)'	System	12 Sep 2020 05:14:25

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:14:18', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '7773a530-02a9-42ef-b2f1-6fd2727b59fe'	System	12 Sep 2020 05:14:25
User entered 'None (1)'	System	12 Sep 2020 05:14:25

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:14:22', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '7773a530-02a9-42ef-b2f1-6fd2727b59fe' User entered '11 Sep 2020 22:14'	System	12 Sep 2020 05:14:25
	System	12 Sep 2020 05:14:25

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 5'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:57:43', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'e902fef1-3156-4f58-bc61-5566723a4bdf' User entered 'None (1)'	System	13 Sep 2020 03:58:48
	System	13 Sep 2020 03:58:48

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:57:55', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'e902fef1-3156-4f58-bc61-5566723a4bdf' User entered 'No (N)'	System	13 Sep 2020 03:58:48
	System	13 Sep 2020 03:58:48

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:57:52', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'e902fef1-3156-4f58-bc61-5566723a4bdf' User entered 'No (N)'	System	13 Sep 2020 03:58:48
	System	13 Sep 2020 03:58:48

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:58:02', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'e902fef1-3156-4f58-bc61-5566723a4bdf' User entered 'None (1)'	System	13 Sep 2020 03:58:48
	System	13 Sep 2020 03:58:48

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:58:07', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'e902fef1-3156-4f58-bc61-5566723a4bdf' User entered '12 Sep 2020 20:58'	System	13 Sep 2020 03:58:48
	System	13 Sep 2020 03:58:48

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 6'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:21:17', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3dc952bc-058b-4855-95d2-78210b6d9099'	System	14 Sep 2020 05:21:39
User entered 'None (1)'	System	14 Sep 2020 05:21:39

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:21:20', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3dc952bc-058b-4855-95d2-78210b6d9099'	System	14 Sep 2020 05:21:39
User entered 'No (N)'	System	14 Sep 2020 05:21:39

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:21:25', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3dc952bc-058b-4855-95d2-78210b6d9099'	System	14 Sep 2020 05:21:39
User entered 'No (N)'	System	14 Sep 2020 05:21:39

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:21:33', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3dc952bc-058b-4855-95d2-78210b6d9099'	System	14 Sep 2020 05:21:39
User entered 'None (1)'	System	14 Sep 2020 05:21:39

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:21:36', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3dc952bc-058b-4855-95d2-78210b6d9099'	System	14 Sep 2020 05:21:39
User entered '13 Sep 2020 22:21'	System	14 Sep 2020 05:21:39

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 7'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:02:25', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'f120f717-67c8-4fcc-bf6d-45fe9e91ee58'	System	15 Sep 2020 03:02:51
User entered 'None (1)'	System	15 Sep 2020 03:02:51

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:02:28', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'f120f717-67c8-4fcc-bf6d-45fe9e91ee58'	System	15 Sep 2020 03:02:51
User entered 'No (N)'	System	15 Sep 2020 03:02:51

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:02:35', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'f120f717-67c8-4fcc-bf6d-45fe9e91ee58'	System	15 Sep 2020 03:02:51
User entered 'No (N)'	System	15 Sep 2020 03:02:51

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:02:45', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'f120f717-67c8-4fcc-bf6d-45fe9e91ee58'	System	15 Sep 2020 03:02:51
User entered 'None (1)'	System	15 Sep 2020 03:02:51

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:02:48', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'f120f717-67c8-4fcc-bf6d-45fe9e91ee58'	System	15 Sep 2020 03:02:51
User entered '14 Sep 2020 20:02'	System	15 Sep 2020 03:02:51

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:05:53', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'cec65b0b-eed7-44a9-9c7e-dda689c1a79b' User entered 'None (0)'	System	09 Sep 2020 00:06:36
	System	09 Sep 2020 00:06:36

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:06:01', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'cec65b0b-eed7-44a9-9c7e-dda689c1a79b' User entered 'None (0)'	System	09 Sep 2020 00:06:36
	System	09 Sep 2020 00:06:36

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:06:06', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'cec65b0b-eed7-44a9-9c7e-dda689c1a79b' User entered 'None (0)'	System	09 Sep 2020 00:06:36
	System	09 Sep 2020 00:06:36

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:06:11', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'cec65b0b-eed7-44a9-9c7e-dda689c1a79b' User entered 'None (0)'	System	09 Sep 2020 00:06:36
	System	09 Sep 2020 00:06:36

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:06:15', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'cec65b0b-eed7-44a9-9c7e-dda689c1a79b' User entered 'None (0)'	System	09 Sep 2020 00:06:36
	System	09 Sep 2020 00:06:36

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:06:18', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'cec65b0b-eed7-44a9-9c7e-dda689c1a79b' User entered 'None (0)'	System	09 Sep 2020 00:06:36
	System	09 Sep 2020 00:06:36

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:06:23', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'cec65b0b-eed7-44a9-9c7e-dda689c1a79b' User entered 'No (N)'	System	09 Sep 2020 00:06:36
	System	09 Sep 2020 00:06:36

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T17:06:32', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'cec65b0b-eed7-44a9-9c7e-dda689c1a79b' User entered '08 Sep 2020 17:06'	System	09 Sep 2020 00:06:36
	System	09 Sep 2020 00:06:36

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '08 Sep 2020 16:43'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '08 Sep 2020 19:13'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:03:26', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '88758e9e-a190-4226-9702-22bee342a9e1' User entered 'None (0)'	System	09 Sep 2020 05:04:10
	System	09 Sep 2020 05:04:10

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:03:35', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '88758e9e-a190-4226-9702-22bee342a9e1' User entered 'None (0)'	System	09 Sep 2020 05:04:10
	System	09 Sep 2020 05:04:10

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:03:38', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '88758e9e-a190-4226-9702-22bee342a9e1' User entered 'None (0)'	System	09 Sep 2020 05:04:10
	System	09 Sep 2020 05:04:10

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:03:41', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '88758e9e-a190-4226-9702-22bee342a9e1' User entered 'None (0)'	System	09 Sep 2020 05:04:10
	System	09 Sep 2020 05:04:10

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:03:44', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '88758e9e-a190-4226-9702-22bee342a9e1' User entered 'None (0)'	System	09 Sep 2020 05:04:10
	System	09 Sep 2020 05:04:10

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:03:46', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '88758e9e-a190-4226-9702-22bee342a9e1' User entered 'None (0)'	System	09 Sep 2020 05:04:10
	System	09 Sep 2020 05:04:10

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:04:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '88758e9e-a190-4226-9702-22bee342a9e1' User entered 'No (N)'	System	09 Sep 2020 05:04:10
	System	09 Sep 2020 05:04:10

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-08T22:04:06', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '88758e9e-a190-4226-9702-22bee342a9e1' User entered '08 Sep 2020 22:04'	System	09 Sep 2020 05:04:10
	System	09 Sep 2020 05:04:10

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '08 Sep 2020 20:08'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 2'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T10:00:22', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'a3c23e7f-8b13-43a8-ac3b-4e1ce65c848f' User entered 'None (0)'	System	10 Sep 2020 17:01:10
	System	10 Sep 2020 17:01:10

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T10:00:24', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'a3c23e7f-8b13-43a8-ac3b-4e1ce65c848f' User entered 'None (0)'	System	10 Sep 2020 17:01:10
	System	10 Sep 2020 17:01:10

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T10:00:28', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'a3c23e7f-8b13-43a8-ac3b-4e1ce65c848f' User entered 'None (0)'	System	10 Sep 2020 17:01:10
	System	10 Sep 2020 17:01:10

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T10:00:32', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'a3c23e7f-8b13-43a8-ac3b-4e1ce65c848f' User entered 'None (0)'	System	10 Sep 2020 17:01:10
	System	10 Sep 2020 17:01:10

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T10:00:35', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'a3c23e7f-8b13-43a8-ac3b-4e1ce65c848f' User entered 'None (0)'	System	10 Sep 2020 17:01:10
	System	10 Sep 2020 17:01:10

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T10:00:38', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'a3c23e7f-8b13-43a8-ac3b-4e1ce65c848f' User entered 'None (0)'	System	10 Sep 2020 17:01:10
	System	10 Sep 2020 17:01:10

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T10:00:45', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'a3c23e7f-8b13-43a8-ac3b-4e1ce65c848f' User entered 'No (N)'	System	10 Sep 2020 17:01:10
	System	10 Sep 2020 17:01:10

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T10:00:52', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'a3c23e7f-8b13-43a8-ac3b-4e1ce65c848f' User entered '10 Sep 2020 10:00'	System	10 Sep 2020 17:01:10
	System	10 Sep 2020 17:01:10

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 3'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:13:05', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c13fd670-690d-4a97-89fc-2d8e36026198' User entered 'None (0)'	System	11 Sep 2020 05:13:31
	System	11 Sep 2020 05:13:31

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:13:08', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c13fd670-690d-4a97-89fc-2d8e36026198' User entered 'None (0)'	System	11 Sep 2020 05:13:31
	System	11 Sep 2020 05:13:31

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:13:11', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c13fd670-690d-4a97-89fc-2d8e36026198' User entered 'None (0)'	System	11 Sep 2020 05:13:31
	System	11 Sep 2020 05:13:31

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:13:17', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c13fd670-690d-4a97-89fc-2d8e36026198' User entered 'None (0)'	System	11 Sep 2020 05:13:31
	System	11 Sep 2020 05:13:31

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:13:19', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c13fd670-690d-4a97-89fc-2d8e36026198' User entered 'None (0)'	System	11 Sep 2020 05:13:31
	System	11 Sep 2020 05:13:31

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:13:22', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c13fd670-690d-4a97-89fc-2d8e36026198' User entered 'None (0)'	System	11 Sep 2020 05:13:31
	System	11 Sep 2020 05:13:31

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:13:26', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c13fd670-690d-4a97-89fc-2d8e36026198' User entered 'No (N)'	System	11 Sep 2020 05:13:31
	System	11 Sep 2020 05:13:31

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-10T22:13:29', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c13fd670-690d-4a97-89fc-2d8e36026198' User entered '10 Sep 2020 22:13'	System	11 Sep 2020 05:13:31
	System	11 Sep 2020 05:13:31

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 4'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:14:30', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '6c14b796-c3dd-47d4-b2a3-f85065bae786' User entered 'None (0)'	System	12 Sep 2020 05:14:59
	System	12 Sep 2020 05:14:59

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:14:32', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '6c14b796-c3dd-47d4-b2a3-f85065bae786' User entered 'None (0)'	System	12 Sep 2020 05:14:59
	System	12 Sep 2020 05:14:59

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:14:35', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '6c14b796-c3dd-47d4-b2a3-f85065bae786' User entered 'None (0)'	System	12 Sep 2020 05:14:59
	System	12 Sep 2020 05:14:59

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:14:38', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '6c14b796-c3dd-47d4-b2a3-f85065bae786' User entered 'None (0)'	System	12 Sep 2020 05:14:59
	System	12 Sep 2020 05:14:59

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:14:41', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '6c14b796-c3dd-47d4-b2a3-f85065bae786' User entered 'None (0)'	System	12 Sep 2020 05:14:59
	System	12 Sep 2020 05:14:59

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:14:43', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '6c14b796-c3dd-47d4-b2a3-f85065bae786' User entered 'None (0)'	System	12 Sep 2020 05:14:59
	System	12 Sep 2020 05:14:59

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:14:54', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '6c14b796-c3dd-47d4-b2a3-f85065bae786' User entered 'No (N)'	System	12 Sep 2020 05:14:59
	System	12 Sep 2020 05:14:59

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-11T22:14:58', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '6c14b796-c3dd-47d4-b2a3-f85065bae786' User entered '11 Sep 2020 22:14'	System	12 Sep 2020 05:14:59
	System	12 Sep 2020 05:14:59

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 5'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:58:12', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8133e849-7b58-4dd7-a667-4735c451f229' User entered 'None (0)'	System	13 Sep 2020 03:58:56
	System	13 Sep 2020 03:58:56

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:58:15', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8133e849-7b58-4dd7-a667-4735c451f229' User entered 'None (0)'	System	13 Sep 2020 03:58:56
	System	13 Sep 2020 03:58:56

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:58:18', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8133e849-7b58-4dd7-a667-4735c451f229' User entered 'None (0)'	System	13 Sep 2020 03:58:56
	System	13 Sep 2020 03:58:56

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:58:22', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8133e849-7b58-4dd7-a667-4735c451f229' User entered 'None (0)'	System	13 Sep 2020 03:58:56
	System	13 Sep 2020 03:58:56

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:58:24', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8133e849-7b58-4dd7-a667-4735c451f229' User entered 'None (0)'	System	13 Sep 2020 03:58:56
	System	13 Sep 2020 03:58:56

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:58:27', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8133e849-7b58-4dd7-a667-4735c451f229' User entered 'None (0)'	System	13 Sep 2020 03:58:56
	System	13 Sep 2020 03:58:56

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:58:34', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8133e849-7b58-4dd7-a667-4735c451f229' User entered 'No (N)'	System	13 Sep 2020 03:58:56
	System	13 Sep 2020 03:58:56

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-12T20:58:42', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8133e849-7b58-4dd7-a667-4735c451f229' User entered '12 Sep 2020 20:58'	System	13 Sep 2020 03:58:56
	System	13 Sep 2020 03:58:56

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 6'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:21:43', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ec3d8ed5-ab4b-4cbd-8a82-1640a9593557' User entered 'None (0)'	System	14 Sep 2020 05:22:06
	System	14 Sep 2020 05:22:06

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:21:45', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ec3d8ed5-ab4b-4cbd-8a82-1640a9593557' User entered 'None (0)'	System	14 Sep 2020 05:22:06
	System	14 Sep 2020 05:22:06

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:21:48', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ec3d8ed5-ab4b-4cbd-8a82-1640a9593557' User entered 'None (0)'	System	14 Sep 2020 05:22:06
	System	14 Sep 2020 05:22:06

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:21:50', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ec3d8ed5-ab4b-4cbd-8a82-1640a9593557' User entered 'None (0)'	System	14 Sep 2020 05:22:06
	System	14 Sep 2020 05:22:06

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:21:53', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ec3d8ed5-ab4b-4cbd-8a82-1640a9593557' User entered 'None (0)'	System	14 Sep 2020 05:22:06
	System	14 Sep 2020 05:22:06

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:21:55', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ec3d8ed5-ab4b-4cbd-8a82-1640a9593557' User entered 'None (0)'	System	14 Sep 2020 05:22:06
	System	14 Sep 2020 05:22:06

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:21:59', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ec3d8ed5-ab4b-4cbd-8a82-1640a9593557' User entered 'No (N)'	System	14 Sep 2020 05:22:06
	System	14 Sep 2020 05:22:06

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-13T22:22:02', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ec3d8ed5-ab4b-4cbd-8a82-1640a9593557' User entered '13 Sep 2020 22:22'	System	14 Sep 2020 05:22:06
	System	14 Sep 2020 05:22:06

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	08 Sep 2020 23:27:42
User entered 'Day 7'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:02:53', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '96708308-4331-4ac4-a29b-69d273e47870' User entered 'None (0)'	System	15 Sep 2020 03:03:25
	System	15 Sep 2020 03:03:25

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:02:55', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '96708308-4331-4ac4-a29b-69d273e47870' User entered 'None (0)'	System	15 Sep 2020 03:03:25
	System	15 Sep 2020 03:03:25

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:02:59', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '96708308-4331-4ac4-a29b-69d273e47870' User entered 'None (0)'	System	15 Sep 2020 03:03:25
	System	15 Sep 2020 03:03:25

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:03:03', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '96708308-4331-4ac4-a29b-69d273e47870' User entered 'None (0)'	System	15 Sep 2020 03:03:25
	System	15 Sep 2020 03:03:25

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:03:05', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '96708308-4331-4ac4-a29b-69d273e47870' User entered 'None (0)'	System	15 Sep 2020 03:03:25
	System	15 Sep 2020 03:03:25

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:03:07', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '96708308-4331-4ac4-a29b-69d273e47870' User entered 'None (0)'	System	15 Sep 2020 03:03:25
	System	15 Sep 2020 03:03:25

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:03:16', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '96708308-4331-4ac4-a29b-69d273e47870' User entered 'No (N)'	System	15 Sep 2020 03:03:25
	System	15 Sep 2020 03:03:25

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-09-14T20:03:20', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '96708308-4331-4ac4-a29b-69d273e47870' User entered '14 Sep 2020 20:03'	System	15 Sep 2020 03:03:25
	System	15 Sep 2020 03:03:25

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 23:27:42

US3162090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 23:27:42

US3162090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 20:04:01

US3162090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '15 Sep 2020'	Cynthia Kunakom (b) (4)	16 Sep 2020 20:04:01
	(b) (4)	

US3162090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 20:04:01

US3162090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered empty.	Cynthia Kunakom (b) (4)	16 Sep 2020 20:04:01
	(b) (4)	

US3162090

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 20:04:05

US3162090

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'I'	System	16 Sep 2020 20:04:05

US3162090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:03:07

US3162090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '22 Sep 2020'	Jared Bradshaw (b) (4)	22 Sep 2020 21:03:07
	(b) (4)	

US3162090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:03:07

US3162090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:03:07

US3162090

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:03:10

US3162090

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'I'	System	22 Sep 2020 21:03:10

US3162090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	30 Sep 2020 03:57:32

US3162090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '29 Sep 2020'	Jared Bradshaw (b) (4)	30 Sep 2020 03:57:32
	(b) (4)	

US3162090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	30 Sep 2020 03:57:32

US3162090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	30 Sep 2020 03:57:32

US3162090

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	30 Sep 2020 03:57:25

US3162090

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'I'	System	30 Sep 2020 03:57:25

US3162090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:06:02

US3162090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '6 Oct 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:06:02

US3162090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[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 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:06:02

US3162090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'VISIT3'	System	07 Oct 2020 02:06:02

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:06:31

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '6 Oct 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:06:31

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '12:52'	Jared Bradshaw (b) (4)	07 Oct 2020 02:06:31
	(b) (4)	

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered '6 Oct 2020 12:52'	System	07 Oct 2020 02:06:31

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '98.4' F	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:06:31

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:06:31

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:06:31

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '72'	Jared Bradshaw (b) (4)	07 Oct 2020 02:06:31
	(b) (4)	

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'bpm'	System	07 Oct 2020 02:06:31

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '11'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:06:31

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'breaths/min'	System	07 Oct 2020 02:06:31

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '88'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:06:31

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'mmHg'	System	07 Oct 2020 02:06:31

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 02:16:06
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:06:44
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		07 Oct 2020 02:06:31
User entered '55'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:06:31

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'mmHg'	System	07 Oct 2020 02:06:31

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53

US3162090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53

US3162090

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:06:53

US3162090

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:06:53

US3162090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:07:01

US3162090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '6 Oct 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:07:01

US3162090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '13:23'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:07:01

US3162090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered '6 Oct 2020 13:23'	System	07 Oct 2020 02:07:01

US3162090

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:07:03

US3162090

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'I'	System	07 Oct 2020 02:07:03

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 64'	System	10 Aug 2020 21:47:48

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-10-10T00:04:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '9e104968-225a-4092-8f32-00e240f77de7'	System	10 Oct 2020 07:04:29
User entered 'No (N)'	System	10 Oct 2020 07:04:29

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Have you been exposed to someone with 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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-10-10T00:04:08', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '9e104968-225a-4092-8f32-00e240f77de7'	System	10 Oct 2020 07:04:29
User entered 'No (N)'	System	10 Oct 2020 07:04:29

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-10-10T00:04:25', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '9e104968-225a-4092-8f32-00e240f77de7' User entered '10 Oct 2020 00:04:25'	System	10 Oct 2020 07:04:29
	System	10 Oct 2020 07:04:29

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 21:47:48

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 71'	System	10 Aug 2020 21:47:48

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-10-18T15:09:06', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'e4157989-947c-45de-a98a-59f482661b66'	System	18 Oct 2020 22:09:25
User entered 'No (N)'	System	18 Oct 2020 22:09:25

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Have you been exposed to someone with 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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-10-18T15:09:12', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'e4157989-947c-45de-a98a-59f482661b66'	System	18 Oct 2020 22:09:25
User entered 'No (N)'	System	18 Oct 2020 22:09:25

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-10-18T15:09:23', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'e4157989-947c-45de-a98a-59f482661b66' User entered '18 Oct 2020 15:09:23'	System	18 Oct 2020 22:09:25
	System	18 Oct 2020 22:09:25

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 21:47:48

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 78'	System	10 Aug 2020 21:47:48

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-10-24T23:29:26', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '852ab270-33d9-4459-a9ca-d2845d4add6f' User entered 'No (N)'	System	25 Oct 2020 06:29:40
	System	25 Oct 2020 06:29:40

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Have you been exposed to someone with 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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-10-24T23:29:33', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '852ab270-33d9-4459-a9ca-d2845d4add6f'	System	25 Oct 2020 06:29:40
User entered 'No (N)'	System	25 Oct 2020 06:29:40

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-10-24T23:29:38', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '852ab270-33d9-4459-a9ca-d2845d4add6f' User entered '24 Oct 2020 23:29:38'	System	25 Oct 2020 06:29:40
	System	25 Oct 2020 06:29:40

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 21:47:48

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 92'	System	10 Aug 2020 21:47:48

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-11-07T07:56:40', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '36b1c466-ea15-4dc8-82d5-5950ebb6b005'	System	07 Nov 2020 15:56:58
User entered 'No (N)'	System	07 Nov 2020 15:56:58

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-11-07T07:56:46', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '36b1c466-ea15-4dc8-82d5-5950ebb6b005'	System	07 Nov 2020 15:56:58
User entered 'No (N)'	System	07 Nov 2020 15:56:58

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-11-07T07:56:55', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '36b1c466-ea15-4dc8-82d5-5950ebb6b005' User entered '07 Nov 2020 07:56:55'	System	07 Nov 2020 15:56:58
	System	07 Nov 2020 15:56:58

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 21:47:48

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered 'Day 99'	System	10 Aug 2020 21:47:48

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-11-16T22:09:54', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '514a1505-37de-44bf-844e-18c76c0138d4'	System	17 Nov 2020 06:10:12
User entered 'No (N)'	System	17 Nov 2020 06:10:12

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Have you been exposed to someone with 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 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-11-16T22:10:01', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '514a1505-37de-44bf-844e-18c76c0138d4'	System	17 Nov 2020 06:10:12
User entered 'No (N)'	System	17 Nov 2020 06:10:12

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-11-16T22:10:10', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '514a1505-37de-44bf-844e-18c76c0138d4' User entered '16 Nov 2020 22:10:10'	System	17 Nov 2020 06:10:12
	System	17 Nov 2020 06:10:12

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 21:47:48

US3162090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:48:13
Data entry locked.	System	10 Aug 2020 21:47:48
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 21:47:48

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-11-21T20:59:46', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '057e602b-50b7-4240-807a-495127d48ad5'	System	22 Nov 2020 05:00:19
User entered 'No (N)'	System	22 Nov 2020 05:00:19

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-11-21T20:59:55', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '057e602b-50b7-4240-807a-495127d48ad5'	System	22 Nov 2020 05:00:19
User entered 'No (N)'	System	22 Nov 2020 05:00:19

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-11-21T21:00:14', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '057e602b-50b7-4240-807a-495127d48ad5'	System	22 Nov 2020 05:00:19
User entered '21 Nov 2020 21:00:14'	System	22 Nov 2020 05:00:19

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-11-25T20:34:11', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8f0d28ba-4eb3-4db3-940a-b7084ce0e984' User entered 'No (N)'	System	26 Nov 2020 04:34:27

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-11-25T20:34:18', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8f0d28ba-4eb3-4db3-940a-b7084ce0e984' User entered 'No (N)'	System	26 Nov 2020 04:34:27

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-11-25T20:34:24', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8f0d28ba-4eb3-4db3-940a-b7084ce0e984' User entered '25 Nov 2020 20:34:24'	System	26 Nov 2020 04:34:27
	System	26 Nov 2020 04:34:27

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-12-02T22:41:16', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ead750e5-a66f-4af0-959b-b25912693c21' User entered 'No (N)'	System	03 Dec 2020 06:41:34
	System	03 Dec 2020 06:41:34

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-12-02T22:41:22', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ead750e5-a66f-4af0-959b-b25912693c21' User entered 'No (N)'	System	03 Dec 2020 06:41:34
	System	03 Dec 2020 06:41:34

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-12-02T22:41:29', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ead750e5-a66f-4af0-959b-b25912693c21' User entered '02 Dec 2020 22:41:29'	System	03 Dec 2020 06:41:34
	System	03 Dec 2020 06:41:34

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-12-09T12:11:18', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'e01ff980-83e9-4bca-9e16-5b2627e84297'	System	09 Dec 2020 20:11:43
User entered 'No (N)'	System	09 Dec 2020 20:11:43

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-12-09T12:11:25', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'e01ff980-83e9-4bca-9e16-5b2627e84297'	System	09 Dec 2020 20:11:43
User entered 'No (N)'	System	09 Dec 2020 20:11:43

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-12-09T12:11:35', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'e01ff980-83e9-4bca-9e16-5b2627e84297' User entered '09 Dec 2020 12:11:35'	System	09 Dec 2020 20:11:43
	System	09 Dec 2020 20:11:43

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-12-16T23:39:09', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '428232fe-5e29-4853-b97b-df9b5136f349' User entered 'No (N)'	System	17 Dec 2020 07:40:08
	System	17 Dec 2020 07:40:08

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-12-16T23:39:45', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '428232fe-5e29-4853-b97b-df9b5136f349' User entered 'No (N)'	System	17 Dec 2020 07:40:08
	System	17 Dec 2020 07:40:08

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-12-16T23:40:05', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '428232fe-5e29-4853-b97b-df9b5136f349' User entered '16 Dec 2020 23:40:05'	System	17 Dec 2020 07:40:08
	System	17 Dec 2020 07:40:08

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-12-24T12:49:38', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '6ea05a6d-86db-46bd-a614-f8d2dc7d9454'	System	24 Dec 2020 20:49:48
User entered 'No (N)'	System	24 Dec 2020 20:49:48

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-12-24T12:49:42', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '6ea05a6d-86db-46bd-a614-f8d2dc7d9454' User entered 'No (N)'	System	24 Dec 2020 20:49:48

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2020-12-24T12:49:47', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '6ea05a6d-86db-46bd-a614-f8d2dc7d9454' User entered '24 Dec 2020 12:49:47'	System	24 Dec 2020 20:49:48
	System	24 Dec 2020 20:49:48

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-01-02T18:20:31', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'db8dbcec-c7cb-49ef-8603-c8b8f14f110b'	System	03 Jan 2021 02:20:46
User entered 'No (N)'	System	03 Jan 2021 02:20:46

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-01-02T18:20:37', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'db8dbcec-c7cb-49ef-8603-c8b8f14f110b'	System	03 Jan 2021 02:20:46
User entered 'No (N)'	System	03 Jan 2021 02:20:46

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-01-02T18:20:42', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'db8dbcec-c7cb-49ef-8603-c8b8f14f110b' User entered '02 Jan 2021 18:20:42'	System	03 Jan 2021 02:20:46
	System	03 Jan 2021 02:20:46

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-01-08T11:51:35', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '2b8827ce-d1e7-4383-b7d0-0bd912408ef4' User entered 'No (N)'	System	08 Jan 2021 19:51:45
	System	08 Jan 2021 19:51:45

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-01-08T11:51:39', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '2b8827ce-d1e7-4383-b7d0-0bd912408ef4' User entered 'No (N)'	System	08 Jan 2021 19:51:45
	System	08 Jan 2021 19:51:45

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-01-08T11:51:42', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '2b8827ce-d1e7-4383-b7d0-0bd912408ef4' User entered '08 Jan 2021 11:51:42'	System	08 Jan 2021 19:51:45
	System	08 Jan 2021 19:51:45

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-01-15T16:28:02', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '80af97e2-f6a3-4c56-b753-f2d136acf5e8'	System	16 Jan 2021 00:28:19
User entered 'No (N)'	System	16 Jan 2021 00:28:19

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-01-15T16:28:07', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '80af97e2-f6a3-4c56-b753-f2d136acf5e8' User entered 'No (N)'	System	16 Jan 2021 00:28:19
	System	16 Jan 2021 00:28:19

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-01-15T16:28:13', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '80af97e2-f6a3-4c56-b753-f2d136acf5e8' User entered '15 Jan 2021 16:28:13'	System	16 Jan 2021 00:28:19
	System	16 Jan 2021 00:28:19

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-01-22T23:08:54', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '08d028bb-1d0a-499d-b2f5-0195f9cff407'	System	23 Jan 2021 07:09:06
User entered 'No (N)'	System	23 Jan 2021 07:09:06

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-01-22T23:08:59', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '08d028bb-1d0a-499d-b2f5-0195f9cff407'	System	23 Jan 2021 07:09:06
User entered 'No (N)'	System	23 Jan 2021 07:09:06

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-01-22T23:09:04', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '08d028bb-1d0a-499d-b2f5-0195f9cff407' User entered '22 Jan 2021 23:09:04'	System	23 Jan 2021 07:09:06
	System	23 Jan 2021 07:09:06

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-01-27T23:38:17', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '5de8d053-0616-42b2-862a-c62de5da1db1' User entered 'No (N)'	System	28 Jan 2021 07:38:30
	System	28 Jan 2021 07:38:30

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-01-27T23:38:22', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '5de8d053-0616-42b2-862a-c62de5da1db1'	System	28 Jan 2021 07:38:30
User entered 'No (N)'	System	28 Jan 2021 07:38:30

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-01-27T23:38:25', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '5de8d053-0616-42b2-862a-c62de5da1db1' User entered '27 Jan 2021 23:38:25'	System	28 Jan 2021 07:38:30

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-02-03T00:14:02', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8c7e831e-4bd9-41a2-87a9-8804b1ffe638' User entered 'No (N)'	System	03 Feb 2021 08:14:16
	System	03 Feb 2021 08:14:16

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-02-03T00:14:09', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8c7e831e-4bd9-41a2-87a9-8804b1ffe638'	System	03 Feb 2021 08:14:16
User entered 'No (N)'	System	03 Feb 2021 08:14:16

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-02-03T00:14:12', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '8c7e831e-4bd9-41a2-87a9-8804b1ffe638'	System	03 Feb 2021 08:14:16
User entered '03 Feb 2021 00:14:12'	System	03 Feb 2021 08:14:16

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-02-10T07:23:18', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '322f7672-8876-489d-b2ea-c839c436a657' User entered 'No (N)'	System	10 Feb 2021 15:23:28
	System	10 Feb 2021 15:23:28

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-02-10T07:23:22', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '322f7672-8876-489d-b2ea-c839c436a657'	System	10 Feb 2021 15:23:28
User entered 'No (N)'	System	10 Feb 2021 15:23:28

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-02-10T07:23:26', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '322f7672-8876-489d-b2ea-c839c436a657' User entered '10 Feb 2021 07:23:26'	System	10 Feb 2021 15:23:28
	System	10 Feb 2021 15:23:28

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-02-17T22:24:20', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'f866b568-93af-4aae-a8de-9424ae3780ea' User entered 'No (N)'	System	18 Feb 2021 06:24:30
	System	18 Feb 2021 06:24:30

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-02-17T22:24:25', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'f866b568-93af-4aae-a8de-9424ae3780ea' User entered 'No (N)'	System	18 Feb 2021 06:24:30
	System	18 Feb 2021 06:24:30

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-02-17T22:24:28', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'f866b568-93af-4aae-a8de-9424ae3780ea' User entered '17 Feb 2021 22:24:28'	System	18 Feb 2021 06:24:30
	System	18 Feb 2021 06:24:30

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-02-24T00:07:59-08:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '5e22603c-72dc-40a0-b7e0-400b25e5225b' User entered 'No (N)'	System	01 Mar 2021 06:18:25
	System	01 Mar 2021 06:18:25

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-02-24T00:08:04-08:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '5e22603c-72dc-40a0-b7e0-400b25e5225b'	System	01 Mar 2021 06:18:25
User entered 'No (N)'	System	01 Mar 2021 06:18:25

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-02-24T00:08:07-08:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '5e22603c-72dc-40a0-b7e0-400b25e5225b' User entered '24 Feb 2021 08:08:07'	System	01 Mar 2021 06:18:25
	System	01 Mar 2021 06:18:25

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-03-03T16:28:35-08:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'b4e1455d-316f-4622-a9db-d4db8df6ead8'	System	04 Mar 2021 00:28:45
User entered 'No (N)'	System	04 Mar 2021 00:28:45

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-03-03T16:28:37-08:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'b4e1455d-316f-4622-a9db-d4db8df6ead8'	System	04 Mar 2021 00:28:45
User entered 'No (N)'	System	04 Mar 2021 00:28:45

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-03-03T16:28:41-08:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'b4e1455d-316f-4622-a9db-d4db8df6ead8'	System	04 Mar 2021 00:28:45
User entered '03 Mar 2021 16:28:41'	System	04 Mar 2021 00:28:45

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-03-10T08:43:19-08:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3b4e7df5-81e0-4563-a540-84bdab5b792d'	System	12 Mar 2021 19:16:18
User entered 'No (N)'	System	12 Mar 2021 19:16:18

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-03-10T08:43:23-08:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3b4e7df5-81e0-4563-a540-84bdab5b792d'	System	12 Mar 2021 19:16:18
User entered 'No (N)'	System	12 Mar 2021 19:16:18

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-03-10T08:43:27-08:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '3b4e7df5-81e0-4563-a540-84bdab5b792d' User entered '10 Mar 2021 08:43:27'	System	12 Mar 2021 19:16:18
	System	12 Mar 2021 19:16:18

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-03-17T21:42:06-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '60c6f4be-4f58-4926-b745-2710c449254d' User entered 'No (N)'	System	18 Mar 2021 04:42:19
	System	18 Mar 2021 04:42:19

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-03-17T21:42:12-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '60c6f4be-4f58-4926-b745-2710c449254d'	System	18 Mar 2021 04:42:19
User entered 'No (N)'	System	18 Mar 2021 04:42:19

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-03-17T21:42:17-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '60c6f4be-4f58-4926-b745-2710c449254d' User entered '17 Mar 2021 21:42:17'	System	18 Mar 2021 04:42:19
	System	18 Mar 2021 04:42:19

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-03-24T23:21:01-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '1a46a7cd-071a-4bf1-8333-db712100fd67'	System	25 Mar 2021 06:21:14
User entered 'No (N)'	System	25 Mar 2021 06:21:14

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-03-24T23:21:08-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '1a46a7cd-071a-4bf1-8333-db712100fd67'	System	25 Mar 2021 06:21:14
User entered 'No (N)'	System	25 Mar 2021 06:21:14

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-03-24T23:21:11-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '1a46a7cd-071a-4bf1-8333-db712100fd67'	System	25 Mar 2021 06:21:14
User entered '24 Mar 2021 23:21:11'	System	25 Mar 2021 06:21:14

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-04-02T12:00:19-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '1eae390c-0343-4427-92d7-25587c4d9cb7'	System	02 Apr 2021 19:00:32
User entered 'No (N)'	System	02 Apr 2021 19:00:32

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-04-02T12:00:23-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '1eae390c-0343-4427-92d7-25587c4d9cb7'	System	02 Apr 2021 19:00:32
User entered 'No (N)'	System	02 Apr 2021 19:00:32

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-04-02T12:00:26-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: '1eae390c-0343-4427-92d7-25587c4d9cb7'	System	02 Apr 2021 19:00:32
User entered '02 Apr 2021 12:00:26'	System	02 Apr 2021 19:00:32

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-04-07T08:10:00-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ba9fd363-f886-464d-a530-d1151b82691b'	System	07 Apr 2021 15:10:14
User entered 'No (N)'	System	07 Apr 2021 15:10:14

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-04-07T08:10:03-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ba9fd363-f886-464d-a530-d1151b82691b'	System	07 Apr 2021 15:10:14
User entered 'No (N)'	System	07 Apr 2021 15:10:14

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-04-07T08:10:07-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ba9fd363-f886-464d-a530-d1151b82691b'	System	07 Apr 2021 15:10:14
User entered '07 Apr 2021 08:10:07'	System	07 Apr 2021 15:10:14

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-04-15T16:44:04-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'eee8803e-c247-46dd-9e4d-774699b6ca08'	System	15 Apr 2021 23:44:15
User entered 'No (N)'	System	15 Apr 2021 23:44:15

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-04-15T16:44:09-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'eee8803e-c247-46dd-9e4d-774699b6ca08'	System	15 Apr 2021 23:44:15
User entered 'No (N)'	System	15 Apr 2021 23:44:15

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-04-15T16:44:12-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'eee8803e-c247-46dd-9e4d-774699b6ca08'	System	15 Apr 2021 23:44:15
User entered '15 Apr 2021 16:44:12'	System	15 Apr 2021 23:44:15

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (937C8429-952A-4D11-B1E6-58F90EF6DC37)', Time: '2021-04-25T11:55:56-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ebd51c6c-026c-4c97-9c4d-7be94230f24f'	System	25 Apr 2021 18:56:54
User entered 'Yes (Y)'	System	25 Apr 2021 18:56:54

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Have you been exposed to someone with 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 (937C8429-952A-4D11-B1E6-58F90EF6DC37)', Time: '2021-04-25T11:56:05-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ebd51c6c-026c-4c97-9c4d-7be94230f24f' User entered 'No (N)'	System	25 Apr 2021 18:56:54
	System	25 Apr 2021 18:56:54

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937C8429-952A-4D11-B1E6-58F90EF6DC37)', Time: '2021-04-25T11:56:13-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ebd51c6c-026c-4c97-9c4d-7be94230f24f' User entered 'No (N)'	System	25 Apr 2021 18:56:54
	System	25 Apr 2021 18:56:54

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937C8429-952A-4D11-B1E6-58F90EF6DC37)', Time: '2021-04-25T11:56:20-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ebd51c6c-026c-4c97-9c4d-7be94230f24f' User entered 'Yes (Y)'	System	25 Apr 2021 18:56:54
	System	25 Apr 2021 18:56:54

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937C8429-952A-4D11-B1E6-58F90EF6DC37)', Time: '2021-04-25T11:56:30-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ebd51c6c-026c-4c97-9c4d-7be94230f24f'	System	25 Apr 2021 18:56:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Apr 2021 18:56:54

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937C8429-952A-4D11-B1E6-58F90EF6DC37)', Time: '2021-04-25T11:56:44-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'ebd51c6c-026c-4c97-9c4d-7be94230f24f'	System	25 Apr 2021 18:56:54
User entered '25 Apr 2021 11:56:44'	System	25 Apr 2021 18:56:54

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[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 (937C8429-952A-4D11-B1E6-58F90EF6DC37)', Time: '2021-04-29T19:55:33-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c7d44c9f-fbe5-47db-b3af-23bd6555a670'	System	30 Apr 2021 02:57:56
User entered 'Yes (Y)'	System	30 Apr 2021 02:57:56

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

Have you been exposed to someone with 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 (937C8429-952A-4D11-B1E6-58F90EF6DC37)', Time: '2021-04-29T19:55:45-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c7d44c9f-fbe5-47db-b3af-23bd6555a670'	System	30 Apr 2021 02:57:56
User entered 'No (N)'	System	30 Apr 2021 02:57:56

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937C8429-952A-4D11-B1E6-58F90EF6DC37)', Time: '2021-04-29T19:55:50-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c7d44c9f-fbe5-47db-b3af-23bd6555a670'	System	30 Apr 2021 02:57:56
User entered 'No (N)'	System	30 Apr 2021 02:57:56

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937C8429-952A-4D11-B1E6-58F90EF6DC37)', Time: '2021-04-29T19:55:56-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c7d44c9f-fbe5-47db-b3af-23bd6555a670'	System	30 Apr 2021 02:57:56
User entered 'Yes (Y)'	System	30 Apr 2021 02:57:56

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937C8429-952A-4D11-B1E6-58F90EF6DC37)', Time: '2021-04-29T19:56:07-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c7d44c9f-fbe5-47db-b3af-23bd6555a670'	System	30 Apr 2021 02:57:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Apr 2021 02:57:56

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937C8429-952A-4D11-B1E6-58F90EF6DC37)', Time: '2021-04-29T19:56:11-07:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'c7d44c9f-fbe5-47db-b3af-23bd6555a670'	System	30 Apr 2021 02:57:56
User entered '29 Apr 2021 19:56:11'	System	30 Apr 2021 02:57:56

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 03:13:07

US3162090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:13:07
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 03:13:07

US3162090

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:28:50

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 18:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-02-28T22:18:41-08:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'cbcc1387-5fc5-46f6-a3be-be0455cef3e9'	System	01 Mar 2021 19:06:17
User entered 'No (N)'	System	01 Mar 2021 19:06:17

US3162090

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:28:50

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5709AEEF-3026-4926-B439-B797C9156F7F)', Time: '2021-02-28T22:19:00-08:00', User OID: 'PatientReportedOutcome (US3162090)', ODM File OID: 'cbcc1387-5fc5-46f6-a3be-be0455cef3e9' User entered '28 Feb 2021 22:19:00'	System	01 Mar 2021 19:06:17
	System	01 Mar 2021 19:06:17

US3162090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	04 Nov 2020 03:06:42

US3162090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '3 Nov 2020'	Jessica Fisher (b) (4)	04 Nov 2020 03:06:42

US3162090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Contact Made (CONTACT MADE)'	Jessica Fisher (b) (4)	04 Nov 2020 03:06:42

US3162090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered empty.	Jessica Fisher (b) (4)	04 Nov 2020 03:06:42

US3162090

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	04 Nov 2020 03:06:45

US3162090

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:11:53
User entered 'I'	System	04 Nov 2020 03:06:45

US3162090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	08 Dec 2020 22:21:21

US3162090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '7 Dec 2020'	Tiffany Williams (b) (4) (b) (4)	08 Dec 2020 22:21:21

US3162090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	08 Dec 2020 22:21:21

US3162090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Tiffany Williams (b) (4) (b) (4)	08 Dec 2020 22:21:21

US3162090

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	08 Dec 2020 22:21:51

US3162090

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User entered 'I'	System	08 Dec 2020 22:21:51

US3162090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	07 Jan 2021 18:26:08

US3162090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '6 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	07 Jan 2021 18:26:08

US3162090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	07 Jan 2021 18:26:08

US3162090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Tiffany Williams (b) (4) (b) (4)	07 Jan 2021 18:26:08

US3162090

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	07 Jan 2021 18:26:15

US3162090

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User entered 'I'	System	07 Jan 2021 18:26:15

US3162090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	08 Feb 2021 23:51:49

US3162090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '5 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	08 Feb 2021 23:51:49

US3162090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	08 Feb 2021 23:51:49

US3162090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Tiffany Williams (b) (4) (b) (4)	08 Feb 2021 23:51:49

US3162090

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	08 Feb 2021 23:51:55

US3162090

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:18:23
User entered 'I'	System	08 Feb 2021 23:51:55

US3162090

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	16 Mar 2021 19:37:18

US3162090

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered '15 Mar 2021'	Tiffany Williams (b) (4) (b) (4)	16 Mar 2021 19:37:18

US3162090

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	16 Mar 2021 19:37:18

US3162090

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User entered 'VISIT4'	System	16 Mar 2021 19:37:18

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 20:01:14

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:01:14

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:01:14

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User entered empty.	System	30 Mar 2021 20:01:14

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:01:14

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:01:14

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:01:14

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:01:14

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User entered empty.	System	30 Mar 2021 20:01:14

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:01:14

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User entered empty.	System	30 Mar 2021 20:01:14

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:01:14

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User entered empty.	System	30 Mar 2021 20:01:14

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:01:14

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User entered empty.	System	30 Mar 2021 20:01:14

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52

US3162090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52

US3162090

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	16 Mar 2021 19:38:15

US3162090

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:53
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	16 Mar 2021 19:38:15
	(b) (4)	

US3162090

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	16 Mar 2021 19:38:53

US3162090

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered '15 Mar 2021'	Tiffany Williams (b) (4) (b) (4)	16 Mar 2021 19:38:53

US3162090

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:53
	(b) (4)	
User entered '10:14'	Tiffany Williams (b) (4)	16 Mar 2021 19:38:53
	(b) (4)	

US3162090

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User entered '15 Mar 2021 10:14'	System	16 Mar 2021 19:38:53

US3162090

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	16 Mar 2021 19:39:02

US3162090

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:01:52
User entered '1'	System	16 Mar 2021 19:39:02

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:28:50

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '11 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 19:53:24

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:28:50

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '14:25'	Judith Kirstein (b) (4)	12 Nov 2020 19:53:24
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:28:50

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User entered '11 Nov 2020 14:25'	System	12 Nov 2020 19:53:24

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:28:50

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'Safety Call (Safety Call)'	Judith Kirstein (b) (4)	12 Nov 2020 19:53:24
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:28:50

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 19:53:24

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Day 1 (Day 1)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '9 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:00:13
Query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' answered with 'Fixed' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	23 Jan 2021 06:03:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Jan 2021 06:03:35
User opened query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 18:01:09
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User entered '%'	System	23 Jan 2021 06:03:35
User entered empty.	System	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Jan 2021 06:03:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:01:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:28:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 20:01:09
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Day 2 (Day 2)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '10 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:00:22
Query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' answered with 'Fixed' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	23 Jan 2021 06:04:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Jan 2021 06:03:35
User opened query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 18:01:20
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User entered '%'	System	23 Jan 2021 06:03:35
User entered empty.	System	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Jan 2021 06:03:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'Moderate (Moderate)'	Judith Kirstein (b) (4)	12 Nov 2020 20:09:49
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 20:09:49
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 20:09:49
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:28:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:09:49

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Day 3 (Day 3)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '11 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:00:30
Query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' answered with 'Fixed' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	23 Jan 2021 06:04:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Jan 2021 06:03:35
User opened query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 18:01:28
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User entered '%'	System	23 Jan 2021 06:03:35
User entered empty.	System	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Jan 2021 06:03:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 20:25:44
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Moderate (Moderate)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 20:25:44
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 20:26:40
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:28:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:25:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'Day 4 (Day 4)'	Judith Kirstein (b) (4)	12 Nov 2020 20:37:44
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '12 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	12 Nov 2020 20:37:44
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '99'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User entered '%'	System	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '98.1' F	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:37:44

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 20:37:44
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:28:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	12 Nov 2020 20:37:44
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Day 5 (Day 5)'	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 20:26:15

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '13 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 20:26:15

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 20:26:15

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '99'	Judith Kirstein (b) (4)	13 Nov 2020 20:26:15
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User entered '%'	System	13 Nov 2020 20:26:15

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '97.5' F	Judith Kirstein (b) (4)	13 Nov 2020 20:26:15
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 20:26:15

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 20:26:15

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 20:26:15
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 20:26:15
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 20:26:15

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 20:26:15

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 20:26:15

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 20:26:15

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 20:26:15

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 20:26:15

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 20:26:15

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 20:26:15
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 20:26:15

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 20:26:15
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 20:26:15

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:28:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:33:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 20:26:15

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Day 6 (Day 6)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '14 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '99'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User entered '%'	System	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '97.8' F	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Nov 2020 22:29:46
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:28:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:29:46

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Day 7 (Day 7)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 04:30:12

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '15 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 04:30:12

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 04:30:12

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '98'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 04:30:12

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User entered '%'	System	16 Nov 2020 04:30:12

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '97.4' F	Judith Kirstein (b) (4)	16 Nov 2020 04:30:12
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:30:12
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 04:30:12

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 04:30:12

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:30:12
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 04:30:12

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 04:30:12

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:30:12
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:30:12
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:30:12
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 04:30:12

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:30:12
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:30:12
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:30:12
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:30:12
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:30:12
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:28:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:34:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 04:30:12

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:28:50

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '12 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:39:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:28:50

[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 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:39:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:28:50

[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 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 17:58:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 17:58:48
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:58:48
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 20:39:09
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:39:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:28:50

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '12 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:39:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:28:50

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:39:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:28:50

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:39:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:28:50

[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 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:39:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:28:50

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:39:09

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:28:50

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	12 Nov 2020 20:39:09
	(b) (4)	

US3162090

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:28:50

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:18
User entered '0'	System	16 Nov 2020 17:58:48

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:28:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User accepted default value 'Day 3 (Day 3)'	Judith Kirstein (b) (4)	14 Nov 2020 22:27:43
	(b) (4)	

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:28:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:27:43

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:28:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '14 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:27:43

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:28:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User accepted default value 'Day 5 (Day 5)'	Judith Kirstein (b) (4)	14 Nov 2020 22:27:43
	(b) (4)	

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:28:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 17:59:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 17:59:23
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:59:23
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 22:27:43
User entered empty.	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:27:43

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:28:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:27:43

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:28:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User accepted default value 'Day 7 (Day 7)'	Judith Kirstein (b) (4)	14 Nov 2020 22:27:43
	(b) (4)	

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:28:50

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 17:59:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 17:59:23
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:59:23
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 22:27:43
User entered empty.	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:27:43

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:28:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:27:43

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:28:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User accepted default value 'Day 9 (Day 9)'	Judith Kirstein (b) (4)	14 Nov 2020 22:27:43
	(b) (4)	

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:28:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 17:59:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 17:59:23
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:59:23
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 22:27:43
User entered empty.	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:27:43

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:28:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 22:27:43
	(b) (4)	

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:28:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User accepted default value 'Day 14 (Day 14)'	Judith Kirstein (b) (4)	14 Nov 2020 22:27:43
	(b) (4)	

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:28:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 17:59:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 17:59:23
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:59:23
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 22:27:43
User entered empty.	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:27:43

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:28:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:27:43

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:28:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User accepted default value 'Day 21 (Day 21)'	Judith Kirstein (b) (4)	14 Nov 2020 22:27:43
	(b) (4)	

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:28:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 17:59:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 17:59:23
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:59:23
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 22:27:43
User entered empty.	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:27:43

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:28:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:27:43

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:28:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User accepted default value 'Day 28 (Day 28)'	Judith Kirstein (b) (4)	14 Nov 2020 22:27:43
	(b) (4)	

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:28:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 17:59:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 17:59:23
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:59:23
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 22:27:43
User entered empty.	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:27:43

US3162090

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:28:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 22:27:43

US3162090

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	12 Nov 2020 20:39:48
	(b) (4)	

US3162090

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	12 Nov 2020 20:39:48
	(b) (4)	

US3162090

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[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 21:31:15
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'Clinic (Clinic)'	Judith Kirstein (b) (4)	12 Nov 2020 20:39:48
	(b) (4)	

US3162090

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User entered 'SICKD1'	System	12 Nov 2020 20:39:48

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	12 Nov 2020 20:41:19
	(b) (4)	

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	12 Nov 2020 20:41:19
	(b) (4)	

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '09:27'	Judith Kirstein (b) (4)	12 Nov 2020 20:41:19
	(b) (4)	

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User entered '12 Nov 2020 09:27'	System	12 Nov 2020 20:41:19

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '74' in	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:41:19
DataPoint set to visible.	System	12 Nov 2020 20:39:48

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '183.4' lb	Judith Kirstein (b) (4)	12 Nov 2020 20:41:19
	(b) (4)	
DataPoint set to visible.	System	12 Nov 2020 20:39:48

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '98.1' F	Judith Kirstein (b) (4)	12 Nov 2020 20:41:19
	(b) (4)	

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'Oral (Oral)'	Judith Kirstein (b) (4)	12 Nov 2020 20:41:19
	(b) (4)	

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	12 Nov 2020 20:41:19
	(b) (4)	

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '76'	Judith Kirstein (b) (4)	12 Nov 2020 20:41:19
	(b) (4)	

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User entered 'bpm'	System	12 Nov 2020 20:41:19

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '16'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:41:19

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User entered 'breaths/min'	System	12 Nov 2020 20:41:19

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '130'	Judith Kirstein (b) (4)	12 Nov 2020 20:41:19
	(b) (4)	

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User entered 'mmHg'	System	12 Nov 2020 20:41:19

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '78'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:41:19

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User entered 'mmHg'	System	12 Nov 2020 20:41:19

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15

US3162090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15

US3162090

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	12 Nov 2020 20:41:32
	(b) (4)	

US3162090

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	12 Nov 2020 20:41:32
	(b) (4)	

US3162090

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:28:50

[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 21:31:15
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	12 Nov 2020 20:41:44
	(b) (4)	

US3162090

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:28:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '12 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:41:44

US3162090

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

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	18 Jan 2021 20:23:25

US3162090

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

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '18 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	18 Jan 2021 20:23:25

US3162090

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

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	18 Jan 2021 20:23:25

US3162090

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

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 20:23:25

US3162090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:50

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '18 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	18 Jan 2021 20:23:42

US3162090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:50

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:40:13

US3162090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:50

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	18 Jan 2021 20:23:42

US3162090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:50

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:40:13

US3162090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:50

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '18 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	18 Jan 2021 20:23:42

US3162090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:50

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	18 Jan 2021 20:23:42

US3162090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:50

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 01:40:39
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	18 Jan 2021 20:23:42

US3162090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:50

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 01:40:39
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4)	18 Jan 2021 20:23:42
	(b) (4)	

US3162090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:50

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	18 Jan 2021 20:23:42

US3162090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:50

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered '1'	System	18 Jan 2021 20:23:42

US3162090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:50

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered 'I'	System	18 Jan 2021 20:23:42

US3162090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '74' in	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '180' lb	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered '23.15895'	System	21 Jan 2021 16:37:18
DataPoint set to visible.	System	18 Jan 2021 20:23:42

US3162090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '74' in	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '180' lb	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered '23.15895'	System	21 Jan 2021 16:37:18
DataPoint set to visible.	System	18 Jan 2021 20:23:42

US3162090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	21 Feb 2021 03:20:01
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:20:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:20:01
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	21 Feb 2021 03:19:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:19:53
User entered '18 Jan 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:19:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:19:53
User entered '10:50' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:19:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered '18 Jan 2021 10:50'	System	21 Feb 2021 03:19:53
User entered empty.	System	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:19:53
User entered '98.6' F reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:19:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:19:53
User entered 'Oral (Oral)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:19:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:19:53
User entered '66' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:19:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered 'bpm'	System	21 Feb 2021 03:19:53
User entered empty.	System	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:19:53
User entered '12' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:19:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered 'breaths/min'	System	21 Feb 2021 03:19:53
User entered empty.	System	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:19:53
User entered '110' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:19:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered 'mmHg'	System	21 Feb 2021 03:19:53
User entered empty.	System	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:19:53
User entered '66' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 03:19:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered 'mmHg'	System	21 Feb 2021 03:19:53
User entered empty.	System	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '74' in	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '180' lb	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered '23.15895'	System	21 Jan 2021 16:37:18
DataPoint set to visible.	System	18 Jan 2021 20:23:42

US3162090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 16:39:50
User entered '18 Jan 2021' reason for change: New Information	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:39:50
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 16:37:18
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 16:39:50
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Jan 2021 16:39:50
User entered '12:38' reason for change: New Information	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:39:50
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 16:37:18
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered '18 Jan 2021 12:38'	System	21 Jan 2021 16:39:50
User entered empty.	System	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 16:39:50
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Jan 2021 16:39:50
User entered '98.1' F reason for change: New Information	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:39:50
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 16:37:18
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Oral (Oral)' reason for change: New Information	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:39:50
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 16:39:50
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Jan 2021 16:39:50
User entered '68' reason for change: New Information	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:39:50
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 16:37:18
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered 'bpm'	System	21 Jan 2021 16:39:50
User entered empty.	System	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 16:39:50
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Jan 2021 16:39:50
User entered '16' reason for change: New Information	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:39:50
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 16:37:18
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered 'breaths/min'	System	21 Jan 2021 16:39:50
User entered empty.	System	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 16:39:50
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Jan 2021 16:39:50
User entered '104' reason for change: New Information	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:39:50
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 16:37:18
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered 'mmHg'	System	21 Jan 2021 16:39:50
User entered empty.	System	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 16:39:50
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Jan 2021 16:39:50
User entered '82' reason for change: New Information	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:39:50
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 16:37:18
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:37:18

US3162090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered 'mmHg'	System	21 Jan 2021 16:39:50
User entered empty.	System	21 Jan 2021 16:37:18

US3162090

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:40:14

US3162090

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:40:14

US3162090

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	18 Jan 2021 20:24:08

US3162090

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Tiffany Williams (b) (4) (b) (4)	18 Jan 2021 20:24:08

US3162090

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Tiffany Williams (b) (4) (b) (4)	18 Jan 2021 20:24:08

US3162090

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered 'mRNA-1273'	System	18 Jan 2021 20:24:08
DataPoint set to visible.	System	18 Jan 2021 20:23:42

US3162090

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '18 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	18 Jan 2021 20:24:08

US3162090

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '12:03'	Tiffany Williams (b) (4) (b) (4)	18 Jan 2021 20:24:08

US3162090

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered '18 Jan 2021 12:03'	System	18 Jan 2021 20:24:08

US3162090

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Left Arm (LEFT ARM)'	Tiffany Williams (b) (4) (b) (4)	18 Jan 2021 20:24:08

US3162090

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered 'ONCE'	System	18 Jan 2021 20:24:08

US3162090

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered 'INTRAMUSCULAR'	System	18 Jan 2021 20:24:08

US3162090

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:41:25

US3162090

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '18 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:41:25

US3162090

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '10:56'	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:41:25

US3162090

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered '18 Jan 2021 10:56'	System	21 Jan 2021 16:41:25

US3162090

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:28:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:41:48

US3162090

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:28:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '18 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:41:48

US3162090

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:28:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '11:02'	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:41:48

US3162090

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:28:50

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered '18 Jan 2021 11:02'	System	21 Jan 2021 16:41:48

US3162090

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

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	21 Jan 2021 16:41:54

US3162090

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

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:19
User entered 'I'	System	21 Jan 2021 16:41:54

US3162090

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:43
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:53
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	15 Feb 2021 19:23:46
	(b) (4)	

US3162090

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:43
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:53
	(b) (4)	
User entered '25 Jan 2021'	Tiffany Williams (b) (4)	15 Feb 2021 19:23:46
	(b) (4)	

US3162090

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:43
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:53
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	15 Feb 2021 19:23:46
	(b) (4)	

US3162090

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:43
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:53
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	15 Feb 2021 19:23:46
	(b) (4)	

US3162090

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:43
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:53
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	15 Feb 2021 19:23:51
	(b) (4)	

US3162090

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:43
User entered '1'	System	15 Feb 2021 19:23:51

US3162090

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:43
User entered 'I'	System	15 Feb 2021 19:23:51
DataPoint set to visible.	System	15 Feb 2021 19:23:51

US3162090

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	15 Feb 2021 19:24:04
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '15 Feb 2021'	Tiffany Williams (b) (4)	15 Feb 2021 19:24:04
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4)	15 Feb 2021 19:24:04
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User entered 'OLD29'	System	15 Feb 2021 19:24:04

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 00:54:48

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '15 Feb 2021'	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '10:41'	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User entered '15 Feb 2021 10:41'	System	18 Feb 2021 00:54:48

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '98.5' F	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered 'Oral (Oral)'	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '75'	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User entered 'bpm'	System	18 Feb 2021 00:54:48

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '12'	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User entered 'breaths/min'	System	18 Feb 2021 00:54:48

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '117'	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User entered 'mmHg'	System	18 Feb 2021 00:54:48

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '61'	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User entered 'mmHg'	System	18 Feb 2021 00:54:48

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 00:54:48

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '15 Feb 2021'	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '11:49'	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User entered '15 Feb 2021 11:49'	System	18 Feb 2021 00:54:48

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '97.7' F	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered 'Oral (Oral)'	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '79'	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User entered 'bpm'	System	18 Feb 2021 00:54:48

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '15'	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User entered 'breaths/min'	System	18 Feb 2021 00:54:48

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '110'	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User entered 'mmHg'	System	18 Feb 2021 00:54:48

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '63'	Tiffany Williams (b) (4)	18 Feb 2021 00:54:48
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User entered 'mmHg'	System	18 Feb 2021 00:54:48

US3162090

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered 'No (N)'	Tiffany Williams (b) (4)	18 Feb 2021 00:55:03
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Feb 2021 00:55:03
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	15 Feb 2021 19:24:31
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	15 Feb 2021 19:24:31
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	15 Feb 2021 19:24:31
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User entered 'mRNA-1273'	System	15 Feb 2021 19:24:31
DataPoint set to visible.	System	15 Feb 2021 19:23:51

US3162090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '15 Feb 2021'	Tiffany Williams (b) (4)	15 Feb 2021 19:24:31
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '11:14'	Tiffany Williams (b) (4)	15 Feb 2021 19:24:31
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User entered '15 Feb 2021 11:14'	System	15 Feb 2021 19:24:31

US3162090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Tiffany Williams (b) (4)	15 Feb 2021 19:24:31
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User entered 'ONCE'	System	15 Feb 2021 19:24:31

US3162090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:50

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User entered 'INTRAMUSCULAR'	System	15 Feb 2021 19:24:31

US3162090

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	15 Feb 2021 19:24:36
	(b) (4)	

US3162090

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:35
User entered 'I'	System	15 Feb 2021 19:24:36

US3162090

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:29
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 18:07:33

US3162090

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:29
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:53
	(b) (4)	
User entered '22 Feb 2021'	Tiffany Williams (b) (4)	23 Feb 2021 18:07:33
	(b) (4)	

US3162090

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:29
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:53
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	23 Feb 2021 18:07:33
	(b) (4)	

US3162090

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:29
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:02:53
User entered empty.	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 18:07:33

US3162090

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:29
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:53
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	23 Feb 2021 18:07:41
	(b) (4)	

US3162090

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:29
User entered 'I'	System	23 Feb 2021 18:07:41

US3162090

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	16 Mar 2021 21:30:11
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '15 Mar 2021'	Tiffany Williams (b) (4)	16 Mar 2021 21:30:11
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4)	16 Mar 2021 21:30:11
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered 'OLD57'	System	16 Mar 2021 21:30:11

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered 'No (N)'	Tiffany Williams (b) (4)	16 Mar 2021 21:30:37
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	16 Mar 2021 21:30:37
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	16 Mar 2021 21:30:37
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered empty.	System	16 Mar 2021 21:30:37

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	16 Mar 2021 21:30:37
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	16 Mar 2021 21:30:37
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	16 Mar 2021 21:30:37
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	16 Mar 2021 21:30:37
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered empty.	System	16 Mar 2021 21:30:37

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	16 Mar 2021 21:30:37
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered empty.	System	16 Mar 2021 21:30:37

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	16 Mar 2021 21:30:37
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered empty.	System	16 Mar 2021 21:30:37

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	16 Mar 2021 21:30:37
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered empty.	System	16 Mar 2021 21:30:37

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01

US3162090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:50

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01

US3162090

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered 'No (N)'	Tiffany Williams (b) (4)	16 Mar 2021 21:30:47
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	16 Mar 2021 21:30:47
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	16 Mar 2021 21:31:04
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '15 Mar 2021'	Tiffany Williams (b) (4)	16 Mar 2021 21:31:04
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:02:52
	(b) (4)	
User entered '10:14'	Tiffany Williams (b) (4)	16 Mar 2021 21:31:04
	(b) (4)	

US3162090

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered '15 Mar 2021 10:14'	System	16 Mar 2021 21:31:04

US3162090

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:28:50

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:42:08
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 21:28:35

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection NOS - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 20:44:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 20:44:33
Data point term sent to Coder	System	12 Nov 2020 20:43:53
User entered 'ACUTE VIRAL INFECTION, UNSPECIFIED'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 17:49:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 17:49:18
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:49:18
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 20:43:44
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '9 Nov 2020'	Judith Kirstein (b) (4)	12 Nov 2020 20:43:44
	(b) (4)	

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User entered empty.	System	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:49:18
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '15 Nov 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:49:18
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User entered empty.	System	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	12 Nov 2020 20:43:44
	(b) (4)	

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	12 Nov 2020 20:43:44
	(b) (4)	

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 09:42:05
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' answered with 'Updated' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	18 Nov 2020 21:16:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	18 Nov 2020 21:16:25
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:45:22
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	18 Nov 2020 21:16:25
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	12 Nov 2020 20:43:44
	(b) (4)	

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:49:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	12 Nov 2020 20:43:44
	(b) (4)	

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User entered '0'	System	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26
User entered 'I'	System	12 Nov 2020 20:43:44

US3162090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:50

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:26

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoidal haemorrhage, LLT: Hemorrhoidal bleeding - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Feb 2021 17:19:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Feb 2021 17:19:46
Data point term sent to Coder	System	13 Feb 2021 03:42:20
User entered 'bleeding internal hemorrhoid'	Jessica Fisher (b) (4) (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '31 Jan 2021'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User entered empty.	System	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '01 Feb 2021'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User entered empty.	System	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered empty.	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'I'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jessica Fisher (b) (4)	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User entered '0'	System	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34
User entered 'I'	System	13 Feb 2021 03:41:38

US3162090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:50

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:29:34

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain exertional - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Apr 2021 17:15:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Apr 2021 17:15:55
Data point term sent to Coder	System	26 Apr 2021 16:39:28
User entered 'Exertional chest pain'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered 'No (N)'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 16:39:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Apr 2021 16:39:40
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	26 Apr 2021 16:39:40
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 16:39:27
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered '1 Apr 2021'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:43:00
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:43:00
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:43:00
User entered '27 Apr 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:43:00
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered 'No (N)'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered '0'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered '0'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered '0'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered '0'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered '0'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered '0'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered '1'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered '0'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered '0'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:43:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:43:00
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:09
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 16:39:27

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'USA-US074-2021-mRNA-1273-P301000022'	System	30 Apr 2021 13:31:26
User entered 'New'	(b) (4), (b) (6)	30 Apr 2021 13:31:26

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Acute myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 23:49:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 23:49:11
Data point term sent to Coder	System	29 Apr 2021 23:48:21
User entered 'acute myocardial infarction'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '27 Apr 2021'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '27 Apr 2021'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Grade 4 (Grade 4)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '1'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '27 Apr 2021'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '29 Apr 2021'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '2'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Subject had been having chest pain with exertion since 01APR2021. On 27APR2021, he awoke with chest pain, presented to ER, underwent coronary artery catheterization which showed 100% occlusion of left anterior descending artery. Stent was placed. Subject went home 29APR2021.'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:50

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 23:47:35

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 23:50:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 23:50:10
Data point term sent to Coder	System	29 Apr 2021 23:49:21
User entered 'coronary artery disease'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '27 Apr 2021'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Grade 3/Severe (Grade 3/Severe)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '1'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '1'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 23:49:09

US3162090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 23:49:09

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:28:50

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 21:29:24

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 21:41:17
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 21:41:17
	(b) (4)	
Data point term sent to Coder	System	12 Aug 2020 21:39:52
User entered 'Atorvastatin'	(b) (4), (b) (6)	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '10'	(b) (4), (b) (6)	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 12:37:41
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	12 Aug 2020 21:39:37
User entered 'UN UNK 2018'	(b) (4), (b) (6)	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:57:28
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:57:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:57:28
User entered '26 Apr 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:57:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 21:39:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PROZAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:37:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:37:46
Data point term sent to Coder User entered 'Prozac'	System Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:48 03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'depression'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '20'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'once daily (QD)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '31 Jul 2020'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '12 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User entered '1'	System	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User entered '1'	System	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:28
User entered '804 (804)'	System	03 Sep 2020 19:36:12

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 19:37:46
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	03 Sep 2020 19:37:46
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 19:36:49
User entered 'Finasteride'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:36:40
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Male pattern baldness'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '1'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'once daily (QD)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'un Jul 2020'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:36:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: AMINO ACIDS, INCL. COMBINATIONS WITH POLYPEPTIDES, PRODUCT: LYSINE, PRODUCTSYNONYM: L-LYSINE [LYSINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 19:39:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 19:39:39
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 19:38:54
User entered 'L-lysine'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:38:37
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Nutritional supplement'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '500'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'once daily (QD)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'un UNK 2012'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:38:37

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 19:40:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 19:40:41
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 19:39:55
User entered 'Vitamin D3'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:39:10
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Nutritional supplement'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '10000'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'IU (IU)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'once daily (QD)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'un UNK 2015'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:39:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: VALERIANA OFFICINALIS, PRODUCTSYNONYM: VALERIAN [VALERIANA OFFICINALIS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 09:24:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 09:24:40
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 19:39:56
User entered 'Valerian'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:39:36
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Nutritional supplement'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '500'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'once daily (QD)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'un UNK 2015'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:39:36

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 19:41:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 19:41:45
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 19:40:57
User entered 'melatonin'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:40:01
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Nutritional supplement'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '3'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'once daily (QD)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'un UNK 2015'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:40:01

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PROZAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 19:41:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 19:41:46
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 19:40:57
User entered 'Prozac'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:40:29
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening PROZAC should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:35:15
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening PROZAC should be recorded, and update con med indication or provide clarification. ' answered with 'The depression did not worsen. His physician started him on 20 mg Prozac, but that dose was not controlling his depression, so his dose was increased to 40. The prozac was not adequately controlling the panic attacks, so a second med was started.' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	04 Oct 2020 00:12:10
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening PROZAC should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 12:33:30
User entered 'Depression'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '40'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'once daily (QD)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '12 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:40:29

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 07:27:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 07:27:32
Data point term sent to Coder	System	03 Sep 2020 19:42:00
User entered 'Lorazepam'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:35:55
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Panic attacks were inadvertently not entered in EDC although they are in MH in source.' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	04 Oct 2020 00:19:50
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 12:32:36
User entered 'Panic attacks'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0.5'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'as needed (PRN)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '12 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 19:41:10

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: AMINO ACIDS, INCL. COMBINATIONS WITH POLYPEPTIDES, PRODUCT: ARGININE, PRODUCTSYNONYM: L-ARGININE [ARGININE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 02:10:29
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 02:10:29
	(b) (4)	
Data point term sent to Coder	System	07 Oct 2020 02:09:19
User entered 'L-arginine'	Jared Bradshaw (b) (4)	07 Oct 2020 02:08:20
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'nutritional supplement'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '700'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '29 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 02:08:20

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYV, PRODUCTSYNONYM: PNEUMOCOCCAL VACCINE POLYVALENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 14:52:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 14:52:26
Data point term sent to Coder	System	07 Oct 2020 02:10:19
User entered 'Pneumococcal Polyvalent Vaccine'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Prophylaxis for pneumococcal bacteria infection'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0.5'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'mL (mL)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'once (ONCE)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Intramuscular (INTRAMUSCULAR)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '05 Oct 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '05 Oct 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User entered empty.	System	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User entered empty.	System	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:37:32
User entered empty.	System	07 Oct 2020 02:09:40

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
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) (b) (4)	12 Nov 2020 20:46:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 20:46:36
Data point term sent to Coder	System	12 Nov 2020 20:45:58
User entered 'ACETAMINOPHEN'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:45:46

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:45:46

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'ACUTE VIRAL INFECTION, UNSPECIFIED'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:45:46

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '1000'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:45:46

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'mg (mg)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:45:46

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:45:46

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'as needed (PRN)'	Judith Kirstein (b) (4)	12 Nov 2020 20:45:46
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	12 Nov 2020 20:45:46
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4)	12 Nov 2020 20:45:46
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:45:46

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '11 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:45:46

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:45:46

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 23:56:35
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:45:46

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '14 Nov 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 23:56:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Nov 2020 20:45:46

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	12 Nov 2020 20:45:46
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User entered empty.	System	12 Nov 2020 20:45:46

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User entered empty.	System	12 Nov 2020 20:45:46

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:20:35
User entered empty.	System	12 Nov 2020 20:45:46

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 17:58:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 17:58:46
Data point term sent to Coder	System	16 Nov 2020 17:58:24
User entered 'FLONASE NASAL SPRAY'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'SEASONAL ALLERGIES'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '50'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'ug (ug)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'once daily (QD)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Nasal (NASAL)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'UN UNK 2010'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '0'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Nov 2020 17:58:23

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:25:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:25:05
Data point term sent to Coder	System	16 Nov 2020 23:58:59
User entered 'ACETAMINOPHEN/DIPHENHYDRAMINE'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 23:58:45

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 23:58:45

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'ACUTE VIRAL INFECTION, UNSPECIFIED'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 23:58:45

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '1000/50'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 23:58:45

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'mg (mg)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 23:58:45

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 23:58:45

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'once (ONCE)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 23:58:45

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	16 Nov 2020 23:58:45
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4)	16 Nov 2020 23:58:45
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	16 Nov 2020 23:58:45
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '14 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 23:58:45

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	16 Nov 2020 23:58:45
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:06:58
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	16 Nov 2020 23:58:45
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered '14 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 23:58:45

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	16 Nov 2020 23:58:45

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User entered empty.	System	16 Nov 2020 23:58:45

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User entered empty.	System	16 Nov 2020 23:58:45

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:28:36
User entered empty.	System	16 Nov 2020 23:58:45

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	30 Apr 2021 15:29:31
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Apr 2021 23:58:17
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Apr 2021 23:58:17
	(b) (4)	
Data point term sent to Coder	System	29 Apr 2021 23:57:27
User entered 'lisinopril'	Judith Kirstein (b) (4)	29 Apr 2021 23:56:52
	(b) (4)	

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'coronary artery disease'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '2.5'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'mg (mg)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'once daily (QD)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '27 Apr 2021'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Apr 2021 23:56:52

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 00:01:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 00:01:12
Data point term sent to Coder	System	29 Apr 2021 23:59:45
User entered 'metoprolol'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'coronary artery disease'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '12.5'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'mg (mg)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'twice daily (BID)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '27 Apr 2021'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Apr 2021 23:58:44

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 06:13:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 06:13:14
Data point term sent to Coder	System	30 Apr 2021 00:00:46
User entered 'rivaroxaban'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'coronary artery disease'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '2.5'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'mg (mg)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'twice daily (BID)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '27 Apr 2021'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 00:00:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 00:02:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 00:02:12
Data point term sent to Coder	System	30 Apr 2021 00:01:47
User entered 'rosuvastatin'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Hyperlipidemia'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '40'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'mg (mg)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'once daily (QD)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '27 Apr 2021'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 00:01:26

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 00:03:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 00:03:12
Data point term sent to Coder	System	30 Apr 2021 00:02:49
User entered 'ticagrelor'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'coronary artery disease'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '90'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'mg (mg)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'twice daily (BID)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '27 Apr 2021'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '0'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 00:02:31

US3162090

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:28:50

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:52:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:52:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:06:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	13 Aug 2020 01:47:13

US3162090

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:28:50

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered '27 Apr 2021'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:52:58

US3162090

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:28:50

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'coronary artery STENT PLACEMENT' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:53:25
User entered 'Stent placement'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:52:58

US3162090

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:28:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:52:58

US3162090

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:28:50

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered empty.	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 23:52:58

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'USA-US074-2021-MRNA-1273-P301000022'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'Yes (Y)'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	30 Apr 2021 15:29:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'No (N)'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'No (N)'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'Yes (Y)'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'No (N)'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'No (N)'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'No (N)'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'Judith'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'Kirstein'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'BANNING'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'CA'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered '92220'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	30 Apr 2021 15:29:31
	(b) (4)	
User entered 'US'	System	30 Apr 2021 13:31:52

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 13:31:52

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'USA-US074-2021-MRNA-1273-P301000022'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'Yes (Y)'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'No (N)'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'No (N)'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'Yes (Y)'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'No (N)'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'No (N)'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'No (N)'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'Judith'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'Kirstein'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'BANNING'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered 'CA'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:31:44
User entered '92220'	System	30 Apr 2021 13:31:26

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	30 Apr 2021 15:29:31
	(b) (4)	
User entered 'US'	System	30 Apr 2021 13:31:52

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 13:31:52

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:28:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	30 Apr 2021 15:29:31
	(b) (4)	
User entered '30/Apr/2021 09:31'	System	30 Apr 2021 13:31:52

US3162090

Folder: SAE USA-US074-2021-MRNA-1273-P301000022

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:28:50

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) (b) (4)	30 Apr 2021 15:29:31
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 13:31:52