

US3162290 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:32:14

All time stamps listed in this document are displayed in GMT

US3162290

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 04:53:40

Generated On: 09 Jun 2021 15:32:14

[Participant ID](#)

US3162290

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

US3162290

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

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

Visit date (dd MMM yyyy)	19 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	SCRN
------------	------

US3162290

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Date of Birth (MMM yyyy)	(b) (6) 1978
Age	42
Age Units	YEARS
Age (Derived)	42
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	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3162290

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Date of Informed Consent (<i>dd MMM yyyy</i>)	19 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" 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

US3162290

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3162290

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Were any significant conditions reported?

Yes ☒
No ☐

US3162290

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Condition	HYPERTENSION
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)	

US3162290

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	17:45 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 17:45
Height (<i>xxx.x</i>)	170.2 cm
Weight (<i>xxx.x</i>)	72.6 kg
BMI (<i>xxx.x</i>)	25.06210 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)	

US3162290

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3162290

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

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

TAX CONSULTANT

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3162290

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

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

Visit date (dd MMM yyyy)	19 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	VISIT1
------------	--------

US3162290

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

What was the date of randomization? (dd MMM yyyy) 19 OCT 2020

What was the participant's randomization number? 117517

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 ☒

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Height	ND - Not Done
Weight	ND - Not Done

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

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)	19 OCT 2020
Time of assessment (00:00-23:59)	17:45 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 17:45
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	100 mmHg
Diastolic Blood Pressure units	MMHG

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	18:54 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 18:54
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

US3162290

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3162290

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

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) 19 OCT 2020

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

Treatment Date and Time (derived) 19 OCT 2020 18:23

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

US3162290

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

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

Collection date (dd MMM yyyy)	19 OCT 2020
-------------------------------	-------------

Collection time (00:00-23:59)	17:56 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	19 OCT 2020 17:56
------------------------------------	-------------------

US3162290

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Collection date (dd MMM yyyy)			19 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	18:00	19 OCT 2020 18:00
Nasopharyngeal Swab 2	No		

US3162290

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 18:58

PC Open Date & Time

19 OCT 2020 18:43

PC Close Date & Time

19 OCT 2020 21:13

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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 97.1 °F

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

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

PC Time Stamp	20 OCT 2020 00:06
PC Open Date & Time	19 OCT 2020 22:08
PC Close Date & Time	20 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

20 OCT 2020 16:44

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:14

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 21:14

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:14

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

97.8 °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

22 OCT 2020 16:56

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

23 OCT 2020 23:28

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:14

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

98.3 °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

24 OCT 2020 23:13

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 17:37

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

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

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

19 OCT 2020 18:59

PC Open Date & Time

19 OCT 2020 18:43

PC Close Date & Time

19 OCT 2020 21:13

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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

20 OCT 2020 00:07

PC Open Date & Time

19 OCT 2020 22:08

PC Close Date & Time

20 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

1

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

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

Yes ☐

No ☒

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

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

20 OCT 2020 16:47

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

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

21 OCT 2020 21:14

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

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

22 OCT 2020 16:57

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

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

23 OCT 2020 23:28

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

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

24 OCT 2020 23:14

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

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

25 OCT 2020 17:38

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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

No ☒

Yes ☐

PC Time stamp	19 OCT 2020 19:00
PC Open Date & Time	19 OCT 2020 18:43
PC Close Date & Time	19 OCT 2020 21:13

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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

No ☒

Yes ☐

PC Time stamp	20 OCT 2020 00:08
PC Open Date & Time	19 OCT 2020 22:08
PC Close Date & Time	20 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

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 ☒

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 16:47
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

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 ☒

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 21:14
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

47 of 2877

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 16:58
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

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

49 of 2877

EAB) (1725)

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

Yes <input type="checkbox"/>	
PC Time stamp	23 OCT 2020 23:29
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

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

51 of 2877

EAB) (1725)

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 23:14
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

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

53 of 2877

EAB) (1725)

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 17:40
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3162290

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3162290

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162290

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3162290

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162290

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162290

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162290

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

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

Visit date (dd MMM yyyy)	16 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	VISIT2
------------	--------

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

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)	16 NOV 2020
Time of assessment (00:00-23:59)	15:06 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 15:06
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

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)	16 NOV 2020
Time of assessment (00:00-23:59)	16:25 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 16:25
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3162290

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

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

US3162290

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

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) 16 NOV 2020

What was the treatment time? (00:00-23:59) 15:51 (24 HR)

Treatment Date and Time (derived) 16 NOV 2020 15:51

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

US3162290

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

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

Collection date (dd MMM yyyy)	16 NOV 2020
-------------------------------	-------------

Collection time (00:00-23:59)	15:30 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	16 NOV 2020 15:30
------------------------------------	-------------------

US3162290

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Collection date (dd MMM yyyy)			16 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:35	16 NOV 2020 15:35
Nasopharyngeal Swab 2	No		

US3162290

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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

99.0 °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

16 NOV 2020 16:30

PC Open Date & Time

16 NOV 2020 16:11

PC Close Date & Time

16 NOV 2020 18:41

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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 97.1 °F

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

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

PC Time Stamp	16 NOV 2020 20:20
PC Open Date & Time	16 NOV 2020 19:36
PC Close Date & Time	17 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:14

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

99.6 °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

17 NOV 2020 21:26

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:14

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 NOV 2020 22:09

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:14

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

98.2 °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

19 NOV 2020 22:05

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:14

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

21 NOV 2020 00:01

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:14

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

97.3 °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

22 NOV 2020 00:03

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 NOV 2020 00:07

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

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

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 NOV 2020 16:31

PC Open Date & Time

16 NOV 2020 16:11

PC Close Date & Time

16 NOV 2020 18:41

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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

16 NOV 2020 20:22

PC Open Date & Time

16 NOV 2020 19:36

PC Close Date & Time

17 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

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

17 NOV 2020 21:26

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

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

18 NOV 2020 22:10

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

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

19 NOV 2020 22:05

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

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

21 NOV 2020 00:01

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

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

22 NOV 2020 00:03

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

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

23 NOV 2020 00:06

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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

No ☒

Yes ☐

PC Time stamp	16 NOV 2020 16:32
PC Open Date & Time	16 NOV 2020 16:11
PC Close Date & Time	16 NOV 2020 18:41

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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

No ☒

Yes ☐

PC Time stamp	16 NOV 2020 20:23
PC Open Date & Time	16 NOV 2020 19:36
PC Close Date & Time	17 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

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 ☒

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

Yes <input type="checkbox"/>	
PC Time stamp	17 NOV 2020 21:27
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

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 ☒

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

Yes <input type="checkbox"/>	
PC Time stamp	18 NOV 2020 22:11
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

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 ☒

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

Yes <input type="checkbox"/>	
PC Time stamp	19 NOV 2020 22:06
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

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
EAB) (1725)

95 of 2877

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

Yes <input type="checkbox"/>	
PC Time stamp	21 NOV 2020 00:01
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

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

97 of 2877

EAB) (1725)

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

Yes <input type="checkbox"/>	
PC Time stamp	22 NOV 2020 00:03
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

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 ☒

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

Yes <input type="checkbox"/>	
PC Time stamp	23 NOV 2020 00:07
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3162290

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162290

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162290

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3162290

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162290

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162290

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:53:47

Generated On: 09 Jun 2021 15:32:14

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

Visit date (dd MMM yyyy)	18 DEC 2020
--------------------------	-------------

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

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

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:53:47

Generated On: 09 Jun 2021 15:32:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 DEC 2020
Time of assessment (00:00-23:59)	15:57 (24 HR)
Vital Signs Date and Time (derived)	18 DEC 2020 15:57
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162290

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

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.

US3162290

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 DEC 2020
Collection time (00:00-23:59)	16:07 (24 HR)
Collection date and time (derived)	18 DEC 2020 16:07

US3162290

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 61
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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 10:53:06
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 68
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	23 DEC 2020 13:37:56
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 DEC 2020 00:06:35
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 JAN 2021 19:59:09

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 00:26:20

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	20 JAN 2021 09:52:57
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

27 JAN 2021 00:04:28

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 04:18:39
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	10 FEB 2021 19:49:12
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 14:25:41

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

24 FEB 2021 15:54:45

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

03 MAR 2021 18:01:15

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	10 MAR 2021 12:04:35
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	17 MAR 2021 14:53:09
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

24 MAR 2021 13:00:47

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

31 MAR 2021 20:26:27

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

07 APR 2021 08:54:59

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 00:36:39

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

21 APR 2021 04:56:11

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 05:02:22

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 257

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

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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="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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 <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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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="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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 <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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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="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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 <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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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°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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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°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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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="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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 649

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

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

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

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

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

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

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 <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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 <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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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="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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

Patient Cloud Close Date & Time	30 OCT 2022 23:59
---	-------------------

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

[Patient Cloud Close Date & Time](#)

13 NOV 2022 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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="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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

[Patient Cloud Close Date & Time](#)

20 NOV 2022 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

[Patient Cloud Close Date & Time](#)

27 NOV 2022 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

[Patient Cloud Close Date & Time](#)

04 DEC 2022 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

[Patient Cloud Close Date & Time](#)

18 DEC 2022 23:59

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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="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"/>

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

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

Patient Cloud Close Date & Time	25 DEC 2022 23:59
---	-------------------

US3162290

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:32:14

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 01:12:13

US3162290

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3162290

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162290

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3162290

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162290

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3162290

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162290

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3162290

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162290

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3162290

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:14

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.

US3162290

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3162290

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

Date of Contact	2 NOV 2020
Time of Contact	09:00
Date and Time of Contact (derived)	2 NOV 2020 09:00
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 OCT 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)

320 of 2877

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 OCT 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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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

325 of 2877

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 OCT 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)

328 of 2877

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

	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	29 OCT 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)

332 of 2877

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

	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	30 OCT 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)

336 of 2877

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

	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	31 OCT 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)

340 of 2877

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

	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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

	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	1 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)

344 of 2877

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

	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)

345 of 2877

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

Symptom Day

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

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

	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	2 NOV 2020
------	------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

348 of 2877

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

349 of 2877

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

Symptom Day

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

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

	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	3 NOV 2020
------	------------

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

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

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

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

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

Cough	None <input 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)

352 of 2877

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

	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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

Symptom Day

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

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

	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	4 NOV 2020
------	------------

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

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

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

Temperature	96.2 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

356 of 2877

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

	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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

Symptom Day

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

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

	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	5 NOV 2020
------	------------

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

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

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

Temperature	96.5 F
-------------	--------

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

Cough	None	<input 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)

360 of 2877

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 15 Feb 2021 04:53:41

Generated On: 09 Jun 2021 15:32:14

Date of Visit	2 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	2 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

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:32:14

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 15 Feb 2021 04:53:45

Generated On: 09 Jun 2021 15:32:14

Date of Contact	11 FEB 2021
Time of Contact	12:45
Date and Time of Contact (derived)	11 FEB 2021 12:45
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>

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

	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	5 FEB 2021
------	------------

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)

367 of 2877

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

	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	6 FEB 2021
------	------------

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)

371 of 2877

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

372 of 2877

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

	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	7 FEB 2021	
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)

375 of 2877

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

	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	8 FEB 2021
------	------------

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)

379 of 2877

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

	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 FEB 2021	
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)

383 of 2877

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

	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 FEB 2021
------	-------------

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)

387 of 2877

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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"/>

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

	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 FEB 2021
------	-------------

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

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

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

Temperature	98.6 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

391 of 2877

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

Symptom Day

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

	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 FEB 2021
------	-------------

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

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

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

Temperature	97.9 F
-------------	--------

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

Cough	None	<input 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)

395 of 2877

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

Symptom Day

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

	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 FEB 2021
------	-------------

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

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

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

Temperature	97.6 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

399 of 2877

EAB) (1725)

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

	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"/>

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

Symptom Day

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

	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 FEB 2021
------	-------------

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

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

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

Temperature	96.8 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)

403 of 2877

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

Symptom Day

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

	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 FEB 2021
------	-------------

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

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

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

Temperature	97.9 F
-------------	--------

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

Cough	None	<input 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)

407 of 2877

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

Symptom Day

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

Date	16 FEB 2021
------	-------------

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

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

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

Temperature	96.8 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

411 of 2877

EAB) (1725)

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

Date of Visit	11 FEB 2021
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	11 FEB 2021
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

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	4 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)	

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	13 FEB 2021
Day 5	Yes	15 FEB 2021
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)	

US3162290

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 NOV 2020
Time of assessment (00:00-23:59)	16:01 (24 HR)
Vital Signs Date and Time (derived)	2 NOV 2020 16:01
Height (xxx.x)	67 in
Weight (xxx.x)	160 lb
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162290

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 NOV 2020

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

US3162290

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 04:53:46

Generated On: 09 Jun 2021 15:32:14

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

2 NOV 2020

US3162290

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

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

Visit date (dd MMM yyyy)	11 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	SICKD1
------------	--------

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	15:01 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 15:01
Height (xxx.x)	67 in
Weight (xxx.x)	179.6 lb
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)	117 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162290

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:53:46

Generated On: 09 Jun 2021 15:32:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3162290

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 04:53:46

Generated On: 09 Jun 2021 15:32:14

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

11 FEB 2021

US3162290

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

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

Visit date (dd MMM yyyy)	24 FEB 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3162290

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

Date of updated informed consent (dd MMM yyyy) 24 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 24 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3162290

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 FEB 2021

Collection time (00:00-23:59)

13:50 (24 HR)

Collection date and time (derived)

24 FEB 2021 13:50

US3162290

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

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

Collection date (dd MMM yyyy)	24 FEB 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	13:51
---------------------------------	-------

Collection Date and Time (derived)	24 FEB 2021 13:51
------------------------------------	-------------------

US3162290

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 04:53:40

Generated On: 09 Jun 2021 15:32:14

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

AEID

Adverse event

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)

26 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

5 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

430 of 2877

EAB) (1725)

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

AEID

Adverse event

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)

05 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 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

432 of 2877

EAB) (1725)

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

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)	

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

AEID	USA-US074-2021-MRNA-1273-P30 1000018
Adverse event	ACUTE LEFT EPIDIDYMO-ORCHITIS
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)	6 MAR 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)	9 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)	10 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	11 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	434 of 2877

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

SUBJECT HAD ONSET OF LEFT
TESTICULAR AND LOW
ABDOMINAL PAIN ON 06MAR21
THAT LED TO ER VISIT ON
10MAR21, AND ADMISSION TO
HOSPITAL OVERNIGHT FROM
10MAR TO 11MAR21. COVID
TEST IN ER WAS NEGATIVE.
TREATED WITH
LEVOFLOXACIN IV AND THEN
PO. TESTICULAR
ULTRASOUND SHOWED LEFT
EPIDIDYMO-ORCHITIS AND
SMALL COMPLEX LEFT
HYDROCELE WITH
SEPTATIONS. NON-CONTRAST
CT OF ABDOMEN AND PELVIS
SHOWED MILD WALL
THICKENING OF THE MID
THROUGH DISTAL RECTUM
WITH PROMINENT
SURROUNDING LYMPH NODES
AND THE LEFT HYDROCELE.
ECG SHOWED SINUS
TACHYCARDIA.
SUBJECT HAD WBC COUNT OF
19,200 K/UL ON 10MAR21,
DOWN TO 13,500 ON 11MAR21.
RAPID CHLAMYDIA AND
GONORRHEA TESTS WERE
NEGATIVE. IN ER, ON 10MAR,
HEART RATE WAS 127 AND
REACHED MAX OF 135, DOWN
TO 101 BY 11MAR21.
DISCHARGED ON
LEVOFLOXACIN 500 MG DAILY
UNTIL 20MAR, IBUPROFEN 600
MG BID, ACETAMINOPHEN 500
MG BID. PER PHONE CALL
WITH SUBJECT ON 15APR21,
PAIN RESOLVED ON 09APR21
AND PAIN MEDS WERE LAST
TAKEN ON 07APR2021.

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

438 of 2877

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

AEID

Adverse event

SINUS TACHYCARDIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

10 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 MAR 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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

440 of 2877

EAB) (1725)

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

442 of 2877

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 04:53:41

Generated On: 09 Jun 2021 15:32:14

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

Yes ☒

No ☐

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

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

Name of Medication CLARITIN

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

445 of 2877

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

Name of Medication MUCINEX DM
(DEXTROMETHORPHAN/GUAIF
ENESIN)

Prophylaxis Yes ☐
No ☒

Indication VIRAL INFECTION,
UNSPECIFIED

Dose per administration 20/400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

447 of 2877

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 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)	28 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication VIRAL INFECTION,
UNSPECIFIED

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

449 of 2877

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

	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)	27 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)		28 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"/>

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

Name of Medication L-ARGININE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

451 of 2877

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input 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"/>

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication VIRAL INFECTION,
UNSPECIFIED

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

453 of 2877

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	07 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

Name of Medication LEVOFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE LEFT
EPIDIDYMO-ORCHITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

455 of 2877

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 MAR 2021
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"/>

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

Name of Medication LEVOFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE LEFT
EPIDIDYMO-ORCHITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

457 of 2877

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 MAR 2021	
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"/>

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication ACUTE LEFT
EPIDIDYMO-ORCHITIS

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)

459 of 2877

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

	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 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication ACUTE LEFT
EPIDIDYMO-ORCHITIS

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

461 of 2877

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

	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 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

Name of Medication MORPHINE SULFATE

Prophylaxis Yes ☐
No ☒

Indication ACUTE LEFT
EPIDIDYMO-ORCHITIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

463 of 2877

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

Name of Medication OXYCODONE/ACETAMINOPHE
N

Prophylaxis Yes ☐
No ☒

Indication ACUTE LEFT
EPIDIDYMO-ORCHITIS

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

465 of 2877

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

Name of Medication 0.9% SALINE

Prophylaxis Yes ☐
No ☒

Indication SINUS TACHYCARDIA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

PER HOUR

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

PRODUCTION RELEASE (v12.003

467 of 2877

EAB) (1725)

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication ACUTE LEFT
EPIDIDYMO-ORCHITIS

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

469 of 2877

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

	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 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	7 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication ACUTE LEFT
EPIDIDYMO-ORCHITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

471 of 2877

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

	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 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	7 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3162290

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3162290

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 24 Apr 2021 23:19:34

Generated On: 09 Jun 2021 15:32:14

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 MAR 2021	CT OF ABDOMEN AND PELVIS WITHOUT CONTRAST	Adverse Event	
10 MAR 2021	TESTICULAR ULTRASOUND	Adverse Event	
10 MAR 2021	ECG	Adverse Event	

US3162290

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:32:14

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

US3162290

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:32:14

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 ☐

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

SAEID	USA-US074-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

SAEID	USA-US074-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/MAR/2021 09:53
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

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

SAEID	USA-US074-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	17/MAR/2021 10:53
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

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

SAEID	USA-US074-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/MAR/2021 09:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form (4)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

SAEID	USA-US074-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	05/APR/2021 11:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form (5)

Data signed: (b) (4) 24 Apr 2021 23:19:35

Generated On: 09 Jun 2021 15:32:14

SAEID	USA-US074-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/APR/2021 09:28
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

US3162290 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

US3162290

Form: Participant Creation

Generated On: 09 Jun 2021 15:32:14

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'US3162290'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Oct 2020 23:03:40

US3162290

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 01:21:16

US3162290

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '19 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Oct 2020 23:03:41

US3162290

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[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 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Oct 2020 01:21:16

US3162290

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered 'SCRN'	System	20 Oct 2020 01:21:16

US3162290

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:14

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered (b) (6) 1978'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Oct 2020 23:03:42

US3162290

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:14

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '42'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:02:21

US3162290

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:14

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered 'YEARS'	System	20 Oct 2020 17:02:21

US3162290

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:14

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered '42'	System	20 Oct 2020 01:22:09

US3162290

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:14

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Male (M)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:02:21

US3162290

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:14

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:02:21

US3162290

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:14

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:02:21

US3162290

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:14

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'I'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:02:21

US3162290

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:14

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:02:21

US3162290

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:14

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:02:21

US3162290

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:14

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:02:21

US3162290

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:02:21

US3162290

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:14

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:02:21

US3162290

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:14

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:02:21

US3162290

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:14

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:02:21

US3162290

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '19 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 01:22:09

US3162290

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered 'Oct 2020'	System	20 Oct 2020 01:22:09

US3162290

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered '2020'	System	20 Oct 2020 01:22:09

US3162290

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:14

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Amendment 4 (4)'	(b) (4), (b) (6)	20 Oct 2020 01:22:09

US3162290

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 01:22:09

US3162290

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:14

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 01:22:09

US3162290

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:14

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 01:22:09

US3162290

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:14

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 01:22:09

US3162290

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:14

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	19 Oct 2020 23:03:41

US3162290

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:14

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered 'I'	System	20 Oct 2020 01:22:16

US3162290

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 01:22:16

US3162290

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:32:14

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:02:38

US3162290

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 17:05:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 17:05:44
Data point term sent to Coder	System	20 Oct 2020 17:04:00
User entered 'Hypertension'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:03:11

US3162290

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'un UNK 2018'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:03:11

US3162290

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:03:11

US3162290

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:03:11

US3162290

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:03:11

US3162290

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:03:11

US3162290

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered 'Jan 2018'	System	20 Oct 2020 17:03:11

US3162290

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered '2018'	System	20 Oct 2020 17:03:11

US3162290

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered empty.	System	20 Oct 2020 17:03:11

US3162290

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered empty.	System	20 Oct 2020 17:03:11

US3162290

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
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)	17 Nov 2020 22:03:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 22:03:53
Data point term sent to Coder	System	17 Nov 2020 22:03:16
User entered 'Seasonal allergies'	(b) (4), (b) (6)	17 Nov 2020 22:03:11

US3162290

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'UN UNK 2015'	(b) (4), (b) (6)	17 Nov 2020 22:03:11

US3162290

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 22:03:11

US3162290

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 22:03:11

US3162290

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 22:03:11

US3162290

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 22:03:11

US3162290

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered 'Jan 2015'	System	17 Nov 2020 22:03:11

US3162290

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered '2015'	System	17 Nov 2020 22:03:11

US3162290

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered empty.	System	17 Nov 2020 22:03:11

US3162290

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered empty.	System	17 Nov 2020 22:03:11

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:04:13

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '19 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:04:13

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '17:45'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:04:13

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered '19 Oct 2020 17:45'	System	20 Oct 2020 17:04:13

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '170.2' cm	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:04:13
DataPoint set to visible.	System	20 Oct 2020 01:22:16

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '72.6' kg	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:04:13
DataPoint set to visible.	System	20 Oct 2020 01:22:16

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered '25.06210'	System	20 Oct 2020 17:04:13
DataPoint set to visible.	System	20 Oct 2020 01:22:16

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered 'kg/m2'	System	20 Oct 2020 17:04:13
DataPoint set to visible.	System	20 Oct 2020 01:22:16

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:04:13

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:04:13

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:04:13

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:04:13

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered 'bpm'	System	20 Oct 2020 17:04:13

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:04:13

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered 'breaths/min'	System	20 Oct 2020 17:04:13

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:04:13

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered 'mmHg'	System	20 Oct 2020 17:04:13

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:04:13

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered 'mmHg'	System	20 Oct 2020 17:04:13

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36

US3162290

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36

US3162290

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:04:55

US3162290

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '19 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:04:55

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

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 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

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 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

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 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

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 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

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 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

[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 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

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 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

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 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

[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 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

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 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

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 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Tax Consultant'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

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 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

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 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

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 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'I'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:05:46

US3162290

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 01:22:34

US3162290

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '19 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 01:22:34

US3162290

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Oct 2020 01:22:34

US3162290

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'VISIT1'	System	20 Oct 2020 01:22:34

US3162290

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '19 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Oct 2020 01:13:28

US3162290

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:14

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '117517'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Oct 2020 01:13:28

US3162290

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:14

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Oct 2020 01:13:28

US3162290

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:14

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)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:08:21

US3162290

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:14

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)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:08:21

US3162290

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:14

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:08:21

US3162290

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:14

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:08:21

US3162290

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:14

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:08:21

US3162290

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:14

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:08:21
DataPoint set to visible.	System	20 Oct 2020 01:22:09

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User accepted default value 'Pre-Dose (PREDOSE)'	Cynthia Kunakom (b) (4)	20 Oct 2020 17:06:36
	(b) (4)	

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '19 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '17:45'	Cynthia Kunakom (b) (4)	20 Oct 2020 17:06:36
	(b) (4)	

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered '19 Oct 2020 17:45'	System	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '36.1' C	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '96'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'bpm'	System	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '16'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'breaths/min'	System	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '140'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'mmHg'	System	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '100'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'mmHg'	System	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:06:36

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User accepted default value 'Post-Dose (POSTDOSE)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:07:26

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:07:26

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '19 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:07:26

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '18:54'	Cynthia Kunakom (b) (4)	20 Oct 2020 17:07:26
	(b) (4)	

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered '19 Oct 2020 18:54'	System	20 Oct 2020 17:07:26

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '36.9' C	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:07:26

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:07:26

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:07:26

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '93'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:07:26

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'bpm'	System	20 Oct 2020 17:07:26

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '15'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:07:26

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'breaths/min'	System	20 Oct 2020 17:07:26

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '146'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:07:26

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'mmHg'	System	20 Oct 2020 17:07:26

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '95'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:07:26

US3162290

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'mmHg'	System	20 Oct 2020 17:07:26

US3162290

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 01:23:38

US3162290

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '19 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 01:23:38

US3162290

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 01:26:10

US3162290

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 01:26:10

US3162290

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

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)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 01:26:10

US3162290

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'MRNA-1273 OR PLACEBO'	System	20 Oct 2020 01:26:10

US3162290

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '19 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 01:26:10

US3162290

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '18:23'	(b) (4), (b) (6)	20 Oct 2020 01:26:10

US3162290

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered '19 Oct 2020 18:23'	System	20 Oct 2020 01:26:10

US3162290

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	20 Oct 2020 01:26:10

US3162290

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'ONCE'	System	20 Oct 2020 01:26:10

US3162290

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'INTRAMUSCULAR'	System	20 Oct 2020 01:26:10

US3162290

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 01:23:01

US3162290

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '19 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 01:23:01

US3162290

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '17:56'	(b) (4), (b) (6)	20 Oct 2020 01:23:01

US3162290

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered '19 Oct 2020 17:56'	System	20 Oct 2020 01:23:01

US3162290

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:32:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '19 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 01:23:20

US3162290

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	20 Oct 2020 01:23:20

US3162290

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 01:23:20

US3162290

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:14

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '18:00'	(b) (4), (b) (6)	20 Oct 2020 01:23:20

US3162290

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered '19 Oct 2020 18:00'	System	20 Oct 2020 01:23:20

US3162290

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	20 Oct 2020 01:23:20

US3162290

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 01:23:20

US3162290

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:14

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 01:23:20

US3162290

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered empty.	System	20 Oct 2020 01:23:20

US3162290

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 01:23:25

US3162290

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'I'	System	20 Oct 2020 01:23:25

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T18:58:38', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '568f86ef-0d6c-43de-b5a9-a6d32aa2b934' User entered 'Yes (Y)'	System	20 Oct 2020 01:58:55
	System	20 Oct 2020 01:58:55

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T18:58:44', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '568f86ef-0d6c-43de-b5a9-a6d32aa2b934' User entered '98.4'	System	20 Oct 2020 01:58:55
	System	20 Oct 2020 01:58:55

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T18:58:49', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '568f86ef-0d6c-43de-b5a9-a6d32aa2b934'	System	20 Oct 2020 01:58:55
User entered 'No (N)'	System	20 Oct 2020 01:58:55

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T18:58:53', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '568f86ef-0d6c-43de-b5a9-a6d32aa2b934'	System	20 Oct 2020 01:58:55
User entered '19 Oct 2020 18:58'	System	20 Oct 2020 01:58:55

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '19 Oct 2020 18:43'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '19 Oct 2020 21:13'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:05:57', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '681d04f6-945f-434d-81c5-e636c377b652'	System	20 Oct 2020 07:06:20
User entered 'Yes (Y)'	System	20 Oct 2020 07:06:20

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:06:04', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '681d04f6-945f-434d-81c5-e636c377b652' User entered '97.1'	System	20 Oct 2020 07:06:20
	System	20 Oct 2020 07:06:20

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:06:08', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '681d04f6-945f-434d-81c5-e636c377b652'	System	20 Oct 2020 07:06:20
User entered 'No (N)'	System	20 Oct 2020 07:06:20

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:06:16', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '681d04f6-945f-434d-81c5-e636c377b652'	System	20 Oct 2020 07:06:20
User entered '20 Oct 2020 00:06'	System	20 Oct 2020 07:06:20

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '19 Oct 2020 22:08'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '20 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 2'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:43:58', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '4d93903a-248b-4394-8b48-7d56173900d4' User entered 'Yes (Y)'	System	20 Oct 2020 23:44:14
	System	20 Oct 2020 23:44:14

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:44:04', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '4d93903a-248b-4394-8b48-7d56173900d4' User entered '97.6'	System	20 Oct 2020 23:44:14
	System	20 Oct 2020 23:44:14

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:44:07', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '4d93903a-248b-4394-8b48-7d56173900d4'	System	20 Oct 2020 23:44:14
User entered 'No (N)'	System	20 Oct 2020 23:44:14

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:44:12', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '4d93903a-248b-4394-8b48-7d56173900d4' User entered '20 Oct 2020 16:44'	System	20 Oct 2020 23:44:14
	System	20 Oct 2020 23:44:14

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '20 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 3'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:13:54', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '8dd5042f-7641-4794-982e-3cd3554da97e' User entered 'Yes (Y)'	System	22 Oct 2020 04:14:11
	System	22 Oct 2020 04:14:11

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:13:58', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '8dd5042f-7641-4794-982e-3cd3554da97e' User entered '97.1'	System	22 Oct 2020 04:14:11
	System	22 Oct 2020 04:14:11

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:14:01', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '8dd5042f-7641-4794-982e-3cd3554da97e' User entered 'No (N)'	System	22 Oct 2020 04:14:11
	System	22 Oct 2020 04:14:11

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:14:07', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '8dd5042f-7641-4794-982e-3cd3554da97e' User entered '21 Oct 2020 21:14'	System	22 Oct 2020 04:14:11
	System	22 Oct 2020 04:14:11

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 4'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:56:46', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '0ec7ab08-a115-4033-85d7-d7ae969c2270' User entered 'Yes (Y)'	System	22 Oct 2020 23:56:59
	System	22 Oct 2020 23:56:59

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:56:51', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '0ec7ab08-a115-4033-85d7-d7ae969c2270' User entered '97.8'	System	22 Oct 2020 23:56:59
	System	22 Oct 2020 23:56:59

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:56:54', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '0ec7ab08-a115-4033-85d7-d7ae969c2270'	System	22 Oct 2020 23:56:59
User entered 'No (N)'	System	22 Oct 2020 23:56:59

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:56:57', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '0ec7ab08-a115-4033-85d7-d7ae969c2270' User entered '22 Oct 2020 16:56'	System	22 Oct 2020 23:56:59
	System	22 Oct 2020 23:56:59

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 5'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:28:01', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '910f1c7a-be44-4dcf-9db5-2ec5a1493fcb' User entered 'Yes (Y)'	System	24 Oct 2020 06:28:19
	System	24 Oct 2020 06:28:19

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:28:08', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '910f1c7a-be44-4dcf-9db5-2ec5a1493fcb' User entered '97.5'	System	24 Oct 2020 06:28:19
	System	24 Oct 2020 06:28:19

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:28:13', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '910f1c7a-be44-4dcf-9db5-2ec5a1493fcb' User entered 'No (N)'	System	24 Oct 2020 06:28:19
	System	24 Oct 2020 06:28:19

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:28:17', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '910f1c7a-be44-4dcf-9db5-2ec5a1493fcb' User entered '23 Oct 2020 23:28'	System	24 Oct 2020 06:28:19
	System	24 Oct 2020 06:28:19

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 6'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:14

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:13:05', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '16aa7bca-e4af-4dcb-9629-faf8737f3c1b' User entered 'Yes (Y)'	System	25 Oct 2020 06:13:22
	System	25 Oct 2020 06:13:22

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:13:13', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '16aa7bca-e4af-4dcb-9629-faf8737f3c1b' User entered '98.3'	System	25 Oct 2020 06:13:22
	System	25 Oct 2020 06:13:22

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:13:16', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '16aa7bca-e4af-4dcb-9629-faf8737f3c1b' User entered 'No (N)'	System	25 Oct 2020 06:13:22
	System	25 Oct 2020 06:13:22

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:13:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '16aa7bca-e4af-4dcb-9629-faf8737f3c1b' User entered '24 Oct 2020 23:13'	System	25 Oct 2020 06:13:22
	System	25 Oct 2020 06:13:22

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 7'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:14

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:37:18', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'f499ed2a-b177-4f21-b0fe-d945d7012cd8' User entered 'Yes (Y)'	System	26 Oct 2020 00:37:40
	System	26 Oct 2020 00:37:40

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:37:23', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'f499ed2a-b177-4f21-b0fe-d945d7012cd8' User entered '97.1'	System	26 Oct 2020 00:37:40
	System	26 Oct 2020 00:37:40

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:37:26', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'f499ed2a-b177-4f21-b0fe-d945d7012cd8'	System	26 Oct 2020 00:37:40
User entered 'No (N)'	System	26 Oct 2020 00:37:40

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:37:28', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'f499ed2a-b177-4f21-b0fe-d945d7012cd8' User entered '25 Oct 2020 17:37'	System	26 Oct 2020 00:37:40
	System	26 Oct 2020 00:37:40

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T18:59:02', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e459c08d-211f-4884-a88a-2eac939ec6ec'	System	20 Oct 2020 01:59:39
User entered 'None (1)'	System	20 Oct 2020 01:59:39

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T18:59:18', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e459c08d-211f-4884-a88a-2eac939ec6ec' User entered 'No (N)'	System	20 Oct 2020 01:59:39
	System	20 Oct 2020 01:59:39

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T18:59:21', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e459c08d-211f-4884-a88a-2eac939ec6ec' User entered 'No (N)'	System	20 Oct 2020 01:59:39
	System	20 Oct 2020 01:59:39

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T18:59:26', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e459c08d-211f-4884-a88a-2eac939ec6ec'	System	20 Oct 2020 01:59:39
User entered 'None (1)'	System	20 Oct 2020 01:59:39

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T18:59:30', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e459c08d-211f-4884-a88a-2eac939ec6ec' User entered '19 Oct 2020 18:59'	System	20 Oct 2020 01:59:39
	System	20 Oct 2020 01:59:39

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '19 Oct 2020 18:43'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '19 Oct 2020 21:13'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:07:13', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd724f3f4-b7e2-4b23-b389-ee750acb6213' User entered 'None (1)'	System	20 Oct 2020 07:07:28
	System	20 Oct 2020 07:07:28

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:07:16', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd724f3f4-b7e2-4b23-b389-ee750acb6213' User entered 'No (N)'	System	20 Oct 2020 07:07:28
	System	20 Oct 2020 07:07:28

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:07:18', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd724f3f4-b7e2-4b23-b389-ee750acb6213' User entered 'No (N)'	System	20 Oct 2020 07:07:28
	System	20 Oct 2020 07:07:28

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:07:23', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd724f3f4-b7e2-4b23-b389-ee750acb6213' User entered 'None (1)'	System	20 Oct 2020 07:07:28
	System	20 Oct 2020 07:07:28

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:07:26', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd724f3f4-b7e2-4b23-b389-ee750acb6213' User entered '20 Oct 2020 00:07'	System	20 Oct 2020 07:07:28
	System	20 Oct 2020 07:07:28

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '19 Oct 2020 22:08'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '20 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 2'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:44:28', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '1d1bdf2f-8265-4abc-8e2f-a67451a7ae39'	System	20 Oct 2020 23:47:23
User entered 'Does not interfere with activity (2)'	System	20 Oct 2020 23:47:23

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:44:41', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '1d1bdf2f-8265-4abc-8e2f-a67451a7ae39'	System	20 Oct 2020 23:47:23
User entered 'Yes (Y)'	System	20 Oct 2020 23:47:23

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:47:06', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '1d1bdf2f-8265-4abc-8e2f-a67451a7ae39' User entered '1'	System	20 Oct 2020 23:47:23
	System	20 Oct 2020 23:47:23

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:47:11', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '1d1bdf2f-8265-4abc-8e2f-a67451a7ae39' User entered 'No (N)'	System	20 Oct 2020 23:47:23
	System	20 Oct 2020 23:47:23

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:47:14', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '1d1bdf2f-8265-4abc-8e2f-a67451a7ae39'	System	20 Oct 2020 23:47:23
User entered 'None (1)'	System	20 Oct 2020 23:47:23

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:47:18', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '1d1bdf2f-8265-4abc-8e2f-a67451a7ae39' User entered '20 Oct 2020 16:47'	System	20 Oct 2020 23:47:23
	System	20 Oct 2020 23:47:23

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '20 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 3'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:14:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '8000b385-a772-4e73-9a25-29505c8e9992'	System	22 Oct 2020 04:14:38
User entered 'Does not interfere with activity (2)'	System	22 Oct 2020 04:14:38

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:14:21', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '8000b385-a772-4e73-9a25-29505c8e9992'	System	22 Oct 2020 04:14:38
User entered 'No (N)'	System	22 Oct 2020 04:14:38

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:14:23', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '8000b385-a772-4e73-9a25-29505c8e9992'	System	22 Oct 2020 04:14:38
User entered 'No (N)'	System	22 Oct 2020 04:14:38

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:14:29', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '8000b385-a772-4e73-9a25-29505c8e9992'	System	22 Oct 2020 04:14:38
User entered 'None (1)'	System	22 Oct 2020 04:14:38

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:14:33', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '8000b385-a772-4e73-9a25-29505c8e9992'	System	22 Oct 2020 04:14:38
User entered '21 Oct 2020 21:14'	System	22 Oct 2020 04:14:38

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 4'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:57:10', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '0f9b6b8e-89b8-4c1f-acc9c8a4af037e9'	System	22 Oct 2020 23:57:23
User entered 'None (1)'	System	22 Oct 2020 23:57:23

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:57:14', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '0f9b6b8e-89b8-4c1f-accc-9c8a4af037e9'	System	22 Oct 2020 23:57:23
User entered 'No (N)'	System	22 Oct 2020 23:57:23

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:57:16', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '0f9b6b8e-89b8-4c1f-accc-9c8a4af037e9' User entered 'No (N)'	System	22 Oct 2020 23:57:23
	System	22 Oct 2020 23:57:23

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:57:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '0f9b6b8e-89b8-4c1f-accc-9c8a4af037e9' User entered 'None (1)'	System	22 Oct 2020 23:57:23
	System	22 Oct 2020 23:57:23

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:57:22', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '0f9b6b8e-89b8-4c1f-acc-9c8a4af037e9' User entered '22 Oct 2020 16:57'	System	22 Oct 2020 23:57:23
	System	22 Oct 2020 23:57:23

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 5'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:28:26', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '74fd23c8-d942-4784-b25b-99044f86d715'	System	24 Oct 2020 06:28:47
User entered 'None (1)'	System	24 Oct 2020 06:28:47

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:28:29', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '74fd23c8-d942-4784-b25b-99044f86d715' User entered 'No (N)'	System	24 Oct 2020 06:28:47
	System	24 Oct 2020 06:28:47

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:28:31', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '74fd23c8-d942-4784-b25b-99044f86d715' User entered 'No (N)'	System	24 Oct 2020 06:28:47
	System	24 Oct 2020 06:28:47

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:28:38', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '74fd23c8-d942-4784-b25b-99044f86d715'	System	24 Oct 2020 06:28:47
User entered 'None (1)'	System	24 Oct 2020 06:28:47

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:28:42', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '74fd23c8-d942-4784-b25b-99044f86d715' User entered '23 Oct 2020 23:28'	System	24 Oct 2020 06:28:47
	System	24 Oct 2020 06:28:47

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 6'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:13:32', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'f4813580-b257-4ae2-b9d5-417a8a23beae' User entered 'None (1)'	System	25 Oct 2020 06:14:09
	System	25 Oct 2020 06:14:09

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:13:34', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'f4813580-b257-4ae2-b9d5-417a8a23beae' User entered 'No (N)'	System	25 Oct 2020 06:14:09
	System	25 Oct 2020 06:14:09

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:13:36', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'f4813580-b257-4ae2-b9d5-417a8a23beae' User entered 'No (N)'	System	25 Oct 2020 06:14:09
	System	25 Oct 2020 06:14:09

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:14:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'f4813580-b257-4ae2-b9d5-417a8a23beae' User entered 'None (1)'	System	25 Oct 2020 06:14:09
	System	25 Oct 2020 06:14:09

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:14:06', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'f4813580-b257-4ae2-b9d5-417a8a23beae' User entered '24 Oct 2020 23:14'	System	25 Oct 2020 06:14:09
	System	25 Oct 2020 06:14:09

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 7'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:37:49', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e5938228-3abb-4d55-9f1b-4e2a97c35145'	System	26 Oct 2020 00:38:28
User entered 'None (1)'	System	26 Oct 2020 00:38:28

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:38:10', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e5938228-3abb-4d55-9f1b-4e2a97c35145' User entered 'No (N)'	System	26 Oct 2020 00:38:28
	System	26 Oct 2020 00:38:28

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:38:21', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e5938228-3abb-4d55-9f1b-4e2a97c35145' User entered 'No (N)'	System	26 Oct 2020 00:38:28
	System	26 Oct 2020 00:38:28

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:38:24', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e5938228-3abb-4d55-9f1b-4e2a97c35145'	System	26 Oct 2020 00:38:28
User entered 'None (1)'	System	26 Oct 2020 00:38:28

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:38:27', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e5938228-3abb-4d55-9f1b-4e2a97c35145' User entered '25 Oct 2020 17:38'	System	26 Oct 2020 00:38:28
	System	26 Oct 2020 00:38:28

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T18:59:37', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '123ee4de-3275-4f2c-ae4-f562e1a4a06d' User entered 'None (0)'	System	20 Oct 2020 02:00:12
	System	20 Oct 2020 02:00:12

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T18:59:42', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '123ee4de-3275-4f2c-ae4-f562e1a4a06d' User entered 'None (0)'	System	20 Oct 2020 02:00:12
	System	20 Oct 2020 02:00:12

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T18:59:45', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '123ee4de-3275-4f2c-ae4-f562e1a4a06d' User entered 'None (0)'	System	20 Oct 2020 02:00:12
	System	20 Oct 2020 02:00:12

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T18:59:48', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '123ee4de-3275-4f2c-ae4-f562e1a4a06d' User entered 'None (0)'	System	20 Oct 2020 02:00:12
	System	20 Oct 2020 02:00:12

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T18:59:50', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '123ee4de-3275-4f2c-ae4-f562e1a4a06d' User entered 'None (0)'	System	20 Oct 2020 02:00:12
	System	20 Oct 2020 02:00:12

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T18:59:53', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '123ee4de-3275-4f2c-ae4-f562e1a4a06d' User entered 'None (0)'	System	20 Oct 2020 02:00:12
	System	20 Oct 2020 02:00:12

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T18:59:56', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '123ee4de-3275-4f2c-ae4-f562e1a4a06d' User entered 'No (N)'	System	20 Oct 2020 02:00:12
	System	20 Oct 2020 02:00:12

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-19T19:00:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '123ee4de-3275-4f2c-ae4-f562e1a4a06d' User entered '19 Oct 2020 19:00'	System	20 Oct 2020 02:00:12
	System	20 Oct 2020 02:00:12

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '19 Oct 2020 18:43'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '19 Oct 2020 21:13'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:08:20', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5129197c-fda4-4e7f-a09b-0d88c61e642c'	System	20 Oct 2020 07:08:43
User entered 'No interference with activity (1)'	System	20 Oct 2020 07:08:43

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:08:23', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5129197c-fda4-4e7f-a09b-0d88c61e642c' User entered 'None (0)'	System	20 Oct 2020 07:08:43
	System	20 Oct 2020 07:08:43

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:08:25', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5129197c-fda4-4e7f-a09b-0d88c61e642c' User entered 'None (0)'	System	20 Oct 2020 07:08:43
	System	20 Oct 2020 07:08:43

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:08:29', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5129197c-fda4-4e7f-a09b-0d88c61e642c' User entered 'None (0)'	System	20 Oct 2020 07:08:43
	System	20 Oct 2020 07:08:43

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:08:31', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5129197c-fda4-4e7f-a09b-0d88c61e642c' User entered 'None (0)'	System	20 Oct 2020 07:08:43
	System	20 Oct 2020 07:08:43

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:08:34', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5129197c-fda4-4e7f-a09b-0d88c61e642c' User entered 'None (0)'	System	20 Oct 2020 07:08:43
	System	20 Oct 2020 07:08:43

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:08:38', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5129197c-fda4-4e7f-a09b-0d88c61e642c' User entered 'No (N)'	System	20 Oct 2020 07:08:43
	System	20 Oct 2020 07:08:43

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T00:08:41', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5129197c-fda4-4e7f-a09b-0d88c61e642c' User entered '20 Oct 2020 00:08'	System	20 Oct 2020 07:08:43
	System	20 Oct 2020 07:08:43

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '19 Oct 2020 22:08'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '20 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 2'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:47:27', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '90b118ed-c7f9-4094-b5f6-5b64e35710f4' User entered 'None (0)'	System	20 Oct 2020 23:47:46
	System	20 Oct 2020 23:47:46

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:47:29', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '90b118ed-c7f9-4094-b5f6-5b64e35710f4' User entered 'None (0)'	System	20 Oct 2020 23:47:46
	System	20 Oct 2020 23:47:46

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:47:32', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '90b118ed-c7f9-4094-b5f6-5b64e35710f4' User entered 'None (0)'	System	20 Oct 2020 23:47:46
	System	20 Oct 2020 23:47:46

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:47:33', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '90b118ed-c7f9-4094-b5f6-5b64e35710f4' User entered 'None (0)'	System	20 Oct 2020 23:47:46
	System	20 Oct 2020 23:47:46

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:47:35', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '90b118ed-c7f9-4094-b5f6-5b64e35710f4' User entered 'None (0)'	System	20 Oct 2020 23:47:46
	System	20 Oct 2020 23:47:46

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:47:37', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '90b118ed-c7f9-4094-b5f6-5b64e35710f4' User entered 'None (0)'	System	20 Oct 2020 23:47:46
	System	20 Oct 2020 23:47:46

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:47:40', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '90b118ed-c7f9-4094-b5f6-5b64e35710f4' User entered 'No (N)'	System	20 Oct 2020 23:47:46
	System	20 Oct 2020 23:47:46

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-20T16:47:43', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '90b118ed-c7f9-4094-b5f6-5b64e35710f4' User entered '20 Oct 2020 16:47'	System	20 Oct 2020 23:47:46
	System	20 Oct 2020 23:47:46

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '20 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 3'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:14:39', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd3102944-988c-474a-ad41-9f11cf0e09f5' User entered 'None (0)'	System	22 Oct 2020 04:14:56
	System	22 Oct 2020 04:14:56

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:14:42', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd3102944-988c-474a-ad41-9f11cf0e09f5'	System	22 Oct 2020 04:14:56
User entered 'No interference with activity (1)'	System	22 Oct 2020 04:14:56

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:14:44', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd3102944-988c-474a-ad41-9f11cf0e09f5' User entered 'None (0)'	System	22 Oct 2020 04:14:56
	System	22 Oct 2020 04:14:56

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:14:46', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd3102944-988c-474a-ad41-9f11cf0e09f5' User entered 'None (0)'	System	22 Oct 2020 04:14:56
	System	22 Oct 2020 04:14:56

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:14:47', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd3102944-988c-474a-ad41-9f11cf0e09f5' User entered 'None (0)'	System	22 Oct 2020 04:14:56
	System	22 Oct 2020 04:14:56

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:14:49', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd3102944-988c-474a-ad41-9f11cf0e09f5' User entered 'None (0)'	System	22 Oct 2020 04:14:56
	System	22 Oct 2020 04:14:56

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:14:51', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd3102944-988c-474a-ad41-9f11cf0e09f5' User entered 'No (N)'	System	22 Oct 2020 04:14:56
	System	22 Oct 2020 04:14:56

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-21T21:14:54', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd3102944-988c-474a-ad41-9f11cf0e09f5' User entered '21 Oct 2020 21:14'	System	22 Oct 2020 04:14:56
	System	22 Oct 2020 04:14:56

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 4'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:57:41', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9983e40f-688c-4bac-9b57-33c5204b3aef' User entered 'None (0)'	System	22 Oct 2020 23:58:05
	System	22 Oct 2020 23:58:05

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:57:47', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9983e40f-688c-4bac-9b57-33c5204b3aef' User entered 'None (0)'	System	22 Oct 2020 23:58:05
	System	22 Oct 2020 23:58:05

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:57:49', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9983e40f-688c-4bac-9b57-33c5204b3aef' User entered 'None (0)'	System	22 Oct 2020 23:58:05
	System	22 Oct 2020 23:58:05

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:57:51', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9983e40f-688c-4bac-9b57-33c5204b3aef' User entered 'None (0)'	System	22 Oct 2020 23:58:05
	System	22 Oct 2020 23:58:05

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:57:54', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9983e40f-688c-4bac-9b57-33c5204b3aef' User entered 'None (0)'	System	22 Oct 2020 23:58:05
	System	22 Oct 2020 23:58:05

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:57:56', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9983e40f-688c-4bac-9b57-33c5204b3aef' User entered 'None (0)'	System	22 Oct 2020 23:58:05
	System	22 Oct 2020 23:58:05

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:57:59', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9983e40f-688c-4bac-9b57-33c5204b3aef' User entered 'No (N)'	System	22 Oct 2020 23:58:05
	System	22 Oct 2020 23:58:05

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-22T16:58:02', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9983e40f-688c-4bac-9b57-33c5204b3aef' User entered '22 Oct 2020 16:58'	System	22 Oct 2020 23:58:05
	System	22 Oct 2020 23:58:05

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 5'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:28:54', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '77222c88-072d-407f-b32b-9fe7e3b21e8b' User entered 'None (0)'	System	24 Oct 2020 06:29:42
	System	24 Oct 2020 06:29:42

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:28:58', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '77222c88-072d-407f-b32b-9fe7e3b21e8b' User entered 'None (0)'	System	24 Oct 2020 06:29:42
	System	24 Oct 2020 06:29:42

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:29:02', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '77222c88-072d-407f-b32b-9fe7e3b21e8b' User entered 'None (0)'	System	24 Oct 2020 06:29:42
	System	24 Oct 2020 06:29:42

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:29:17', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '77222c88-072d-407f-b32b-9fe7e3b21e8b' User entered 'None (0)'	System	24 Oct 2020 06:29:42
	System	24 Oct 2020 06:29:42

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:29:21', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '77222c88-072d-407f-b32b-9fe7e3b21e8b' User entered 'None (0)'	System	24 Oct 2020 06:29:42
	System	24 Oct 2020 06:29:42

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:29:24', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '77222c88-072d-407f-b32b-9fe7e3b21e8b' User entered 'None (0)'	System	24 Oct 2020 06:29:42
	System	24 Oct 2020 06:29:42

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:29:33', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '77222c88-072d-407f-b32b-9fe7e3b21e8b' User entered 'No (N)'	System	24 Oct 2020 06:29:42
	System	24 Oct 2020 06:29:42

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-23T23:29:36', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '77222c88-072d-407f-b32b-9fe7e3b21e8b' User entered '23 Oct 2020 23:29'	System	24 Oct 2020 06:29:42
	System	24 Oct 2020 06:29:42

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 6'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:14:10', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9f62e3bb-8f15-4401-9c6b-a12bd93816d4' User entered 'None (0)'	System	25 Oct 2020 06:14:35
	System	25 Oct 2020 06:14:35

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:14:18', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9f62e3bb-8f15-4401-9c6b-a12bd93816d4' User entered 'None (0)'	System	25 Oct 2020 06:14:35
	System	25 Oct 2020 06:14:35

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:14:20', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9f62e3bb-8f15-4401-9c6b-a12bd93816d4' User entered 'None (0)'	System	25 Oct 2020 06:14:35
	System	25 Oct 2020 06:14:35

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:14:22', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9f62e3bb-8f15-4401-9c6b-a12bd93816d4' User entered 'None (0)'	System	25 Oct 2020 06:14:35
	System	25 Oct 2020 06:14:35

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:14:24', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9f62e3bb-8f15-4401-9c6b-a12bd93816d4' User entered 'None (0)'	System	25 Oct 2020 06:14:35
	System	25 Oct 2020 06:14:35

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:14:27', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9f62e3bb-8f15-4401-9c6b-a12bd93816d4' User entered 'None (0)'	System	25 Oct 2020 06:14:35
	System	25 Oct 2020 06:14:35

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:14:30', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9f62e3bb-8f15-4401-9c6b-a12bd93816d4' User entered 'No (N)'	System	25 Oct 2020 06:14:35
	System	25 Oct 2020 06:14:35

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-24T23:14:33', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9f62e3bb-8f15-4401-9c6b-a12bd93816d4' User entered '24 Oct 2020 23:14'	System	25 Oct 2020 06:14:35
	System	25 Oct 2020 06:14:35

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	20 Oct 2020 01:26:10
User entered 'Day 7'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:38:36', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '252dec16-b323-49cc-b626-618be969a3bc' User entered 'None (0)'	System	26 Oct 2020 00:41:02
	System	26 Oct 2020 00:41:02

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:38:39', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '252dec16-b323-49cc-b626-618be969a3bc' User entered 'None (0)'	System	26 Oct 2020 00:41:02
	System	26 Oct 2020 00:41:02

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:38:41', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '252dec16-b323-49cc-b626-618be969a3bc' User entered 'None (0)'	System	26 Oct 2020 00:41:02
	System	26 Oct 2020 00:41:02

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:38:43', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '252dec16-b323-49cc-b626-618be969a3bc' User entered 'None (0)'	System	26 Oct 2020 00:41:02
	System	26 Oct 2020 00:41:02

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:38:45', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '252dec16-b323-49cc-b626-618be969a3bc' User entered 'None (0)'	System	26 Oct 2020 00:41:02
	System	26 Oct 2020 00:41:02

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:38:48', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '252dec16-b323-49cc-b626-618be969a3bc' User entered 'None (0)'	System	26 Oct 2020 00:41:02
	System	26 Oct 2020 00:41:02

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:40:57', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '252dec16-b323-49cc-b626-618be969a3bc' User entered 'No (N)'	System	26 Oct 2020 00:41:02
	System	26 Oct 2020 00:41:02

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-10-25T17:40:59', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '252dec16-b323-49cc-b626-618be969a3bc' User entered '25 Oct 2020 17:40'	System	26 Oct 2020 00:41:02
	System	26 Oct 2020 00:41:02

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 01:26:10

US3162290

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 01:26:10

US3162290

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	27 Oct 2020 03:57:20

US3162290

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '26 Oct 2020'	Jessica Fisher (b) (4)	27 Oct 2020 03:57:20

US3162290

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Contact Made (CONTACT MADE)'	Jessica Fisher (b) (4)	27 Oct 2020 03:57:20

US3162290

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Jessica Fisher (b) (4)	27 Oct 2020 03:57:20

US3162290

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	27 Oct 2020 03:57:28

US3162290

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'I'	System	27 Oct 2020 03:57:28

US3162290

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 19:01:31

US3162290

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '2 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 19:01:31

US3162290

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Nov 2020 19:01:31

US3162290

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:01:31

US3162290

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 19:01:37

US3162290

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'I'	System	04 Nov 2020 19:01:37

US3162290

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 01:15:53

US3162290

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '9 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 01:15:53

US3162290

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Nov 2020 01:15:53

US3162290

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 01:15:53

US3162290

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 01:15:59

US3162290

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'I'	System	11 Nov 2020 01:15:59

US3162290

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 21:51:29

US3162290

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 21:51:29

US3162290

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Nov 2020 21:51:29

US3162290

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'VISIT2'	System	17 Nov 2020 21:51:29

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '15:06'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered '16 Nov 2020 15:06'	System	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '99.0' F	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '86'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'bpm'	System	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '14'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'breaths/min'	System	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '139'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'mmHg'	System	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '89'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'mmHg'	System	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '16:25'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered '16 Nov 2020 16:25'	System	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '99.0' F	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '86'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'bpm'	System	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '14'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'breaths/min'	System	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '133'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'mmHg'	System	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '86'	(b) (4), (b) (6)	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'mmHg'	System	17 Nov 2020 21:55:27

US3162290

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 21:56:07

US3162290

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 21:56:07

US3162290

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 00:18:35

US3162290

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 00:18:35

US3162290

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

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)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 00:18:35

US3162290

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'MRNA-1273 OR PLACEBO'	System	17 Nov 2020 00:18:35

US3162290

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 00:18:35

US3162290

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '15:51'	(b) (4), (b) (6)	17 Nov 2020 00:18:35

US3162290

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered '16 Nov 2020 15:51'	System	17 Nov 2020 00:18:35

US3162290

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	17 Nov 2020 00:18:35

US3162290

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'ONCE'	System	17 Nov 2020 00:18:35

US3162290

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:14

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'INTRAMUSCULAR'	System	17 Nov 2020 00:18:35

US3162290

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 21:56:29

US3162290

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 21:56:29

US3162290

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '15:30'	(b) (4), (b) (6)	17 Nov 2020 21:56:29

US3162290

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered '16 Nov 2020 15:30'	System	17 Nov 2020 21:56:29

US3162290

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:32:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 21:56:56

US3162290

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	17 Nov 2020 21:56:56

US3162290

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 21:56:56

US3162290

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:14

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '15:35'	(b) (4), (b) (6)	17 Nov 2020 21:56:56

US3162290

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered '16 Nov 2020 15:35'	System	17 Nov 2020 21:56:56

US3162290

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	17 Nov 2020 21:56:56

US3162290

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 21:56:56

US3162290

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 21:56:56

US3162290

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered empty.	System	17 Nov 2020 21:56:56

US3162290

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 21:57:02

US3162290

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'I'	System	17 Nov 2020 21:57:02

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:30:32', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '06fe0a4e-36b6-4975-bd71-48ae6727629c' User entered 'Yes (Y)'	System	17 Nov 2020 00:32:43
	System	17 Nov 2020 00:32:43

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:30:49', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '06fe0a4e-36b6-4975-bd71-48ae6727629c' User entered '99.0'	System	17 Nov 2020 00:32:43
	System	17 Nov 2020 00:32:43

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:30:53', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '06fe0a4e-36b6-4975-bd71-48ae6727629c' User entered 'No (N)'	System	17 Nov 2020 00:32:43
	System	17 Nov 2020 00:32:43

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:30:59', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '06fe0a4e-36b6-4975-bd71-48ae6727629c' User entered '16 Nov 2020 16:30'	System	17 Nov 2020 00:32:43
	System	17 Nov 2020 00:32:43

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '16 Nov 2020 16:11'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '16 Nov 2020 18:41'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 1, after vaccination (at home)'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:19:39', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '57662887-8707-448a-b3dc-bca2f61e3d1a' User entered 'Yes (Y)'	System	17 Nov 2020 04:20:41
	System	17 Nov 2020 04:20:41

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:20:27', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '57662887-8707-448a-b3dc-bca2f61e3d1a' User entered '97.1'	System	17 Nov 2020 04:20:41
	System	17 Nov 2020 04:20:41

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:20:34', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '57662887-8707-448a-b3dc-bca2f61e3d1a' User entered 'No (N)'	System	17 Nov 2020 04:20:41
	System	17 Nov 2020 04:20:41

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:20:37', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '57662887-8707-448a-b3dc-bca2f61e3d1a'	System	17 Nov 2020 04:20:41
User entered '16 Nov 2020 20:20'	System	17 Nov 2020 04:20:41

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '16 Nov 2020 19:36'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '17 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 2'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:14

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:26:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '690f80a9-7501-4c88-b6f7-66df3e01bc1f' User entered 'Yes (Y)'	System	18 Nov 2020 05:26:14
	System	18 Nov 2020 05:26:14

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:26:05', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '690f80a9-7501-4c88-b6f7-66df3e01bc1f' User entered '99.6'	System	18 Nov 2020 05:26:14
	System	18 Nov 2020 05:26:14

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:26:09', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '690f80a9-7501-4c88-b6f7-66df3e01bc1f' User entered 'No (N)'	System	18 Nov 2020 05:26:14
	System	18 Nov 2020 05:26:14

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:26:12', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '690f80a9-7501-4c88-b6f7-66df3e01bc1f' User entered '17 Nov 2020 21:26'	System	18 Nov 2020 05:26:14
	System	18 Nov 2020 05:26:14

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '17 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '18 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 3'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:14

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:09:38', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '669955f7-f0a3-4656-baf5-16017c402f71' User entered 'Yes (Y)'	System	19 Nov 2020 06:09:55
	System	19 Nov 2020 06:09:55

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:09:42', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '669955f7-f0a3-4656-baf5-16017c402f71' User entered '98.1'	System	19 Nov 2020 06:09:55
	System	19 Nov 2020 06:09:55

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:09:46', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '669955f7-f0a3-4656-baf5-16017c402f71'	System	19 Nov 2020 06:09:55
User entered 'No (N)'	System	19 Nov 2020 06:09:55

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:09:52', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '669955f7-f0a3-4656-baf5-16017c402f71' User entered '18 Nov 2020 22:09'	System	19 Nov 2020 06:09:55
	System	19 Nov 2020 06:09:55

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '18 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '19 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 4'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:14

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:05:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'bbd233e7-ba35-4168-a2a6-7d5d775db014'	System	20 Nov 2020 06:05:32
User entered 'Yes (Y)'	System	20 Nov 2020 06:05:32

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:05:23', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'bbd233e7-ba35-4168-a2a6-7d5d775db014' User entered '98.2'	System	20 Nov 2020 06:05:32
	System	20 Nov 2020 06:05:32

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:05:26', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'bbd233e7-ba35-4168-a2a6-7d5d775db014'	System	20 Nov 2020 06:05:32
User entered 'No (N)'	System	20 Nov 2020 06:05:32

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:05:30', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'bbd233e7-ba35-4168-a2a6-7d5d775db014' User entered '19 Nov 2020 22:05'	System	20 Nov 2020 06:05:32
	System	20 Nov 2020 06:05:32

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '19 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '20 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 5'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:14

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:11', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '6a3080e2-1653-4f50-a61d-d14f6ca9037c' User entered 'Yes (Y)'	System	21 Nov 2020 08:01:23
	System	21 Nov 2020 08:01:23

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:16', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '6a3080e2-1653-4f50-a61d-d14f6ca9037c' User entered '98.2'	System	21 Nov 2020 08:01:23
	System	21 Nov 2020 08:01:23

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '6a3080e2-1653-4f50-a61d-d14f6ca9037c' User entered 'No (N)'	System	21 Nov 2020 08:01:23
	System	21 Nov 2020 08:01:23

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:21', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '6a3080e2-1653-4f50-a61d-d14f6ca9037c' User entered '21 Nov 2020 00:01'	System	21 Nov 2020 08:01:23
	System	21 Nov 2020 08:01:23

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '20 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '21 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 6'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:14

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:02:47', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '76a23aa3-2997-443f-9b9d-07e22ddb32dd' User entered 'Yes (Y)'	System	22 Nov 2020 08:03:03
	System	22 Nov 2020 08:03:03

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:02:53', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '76a23aa3-2997-443f-9b9d-07e22ddb32dd' User entered '97.3'	System	22 Nov 2020 08:03:03
	System	22 Nov 2020 08:03:03

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:02:57', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '76a23aa3-2997-443f-9b9d-07e22ddb32dd' User entered 'No (N)'	System	22 Nov 2020 08:03:03
	System	22 Nov 2020 08:03:03

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:03:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '76a23aa3-2997-443f-9b9d-07e22ddb32dd' User entered '22 Nov 2020 00:03'	System	22 Nov 2020 08:03:03
	System	22 Nov 2020 08:03:03

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '21 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '22 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 7'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:14

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:07:17', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9d1dd563-ff05-4f1c-a8b4-8bd0ccf482b8' User entered 'Yes (Y)'	System	23 Nov 2020 08:07:32
	System	23 Nov 2020 08:07:32

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:07:23', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9d1dd563-ff05-4f1c-a8b4-8bd0ccf482b8' User entered '98.1'	System	23 Nov 2020 08:07:32
	System	23 Nov 2020 08:07:32

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:07:25', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9d1dd563-ff05-4f1c-a8b4-8bd0ccf482b8'	System	23 Nov 2020 08:07:32
User entered 'No (N)'	System	23 Nov 2020 08:07:32

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:07:28', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '9d1dd563-ff05-4f1c-a8b4-8bd0ccf482b8' User entered '23 Nov 2020 00:07'	System	23 Nov 2020 08:07:32
	System	23 Nov 2020 08:07:32

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '22 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '23 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:31:14', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '58ed08f0-abd4-46cf-8acf-3b48adf34cfb'	System	17 Nov 2020 00:32:44
User entered 'None (1)'	System	17 Nov 2020 00:32:44

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:31:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '58ed08f0-abd4-46cf-8acf-3b48adf34cfb' User entered 'No (N)'	System	17 Nov 2020 00:32:44
	System	17 Nov 2020 00:32:44

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:31:22', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '58ed08f0-abd4-46cf-8acf-3b48adf34cfb' User entered 'No (N)'	System	17 Nov 2020 00:32:44
	System	17 Nov 2020 00:32:44

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:31:27', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '58ed08f0-abd4-46cf-8acf-3b48adf34cfb'	System	17 Nov 2020 00:32:44
User entered 'None (1)'	System	17 Nov 2020 00:32:44

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:31:33', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '58ed08f0-abd4-46cf-8acf-3b48adf34cfb' User entered '16 Nov 2020 16:31'	System	17 Nov 2020 00:32:44
	System	17 Nov 2020 00:32:44

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '16 Nov 2020 16:11'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '16 Nov 2020 18:41'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 1, after vaccination (at home)'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:20:47', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c1ace06c-113b-48ba-b60d-b89ce45aee98'	System	17 Nov 2020 04:22:26
User entered 'Does not interfere with activity (2)'	System	17 Nov 2020 04:22:26

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:20:53', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c1ace06c-113b-48ba-b60d-b89ce45aee98'	System	17 Nov 2020 04:22:26
User entered 'No (N)'	System	17 Nov 2020 04:22:26

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:22:14', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c1ace06c-113b-48ba-b60d-b89ce45aee98'	System	17 Nov 2020 04:22:26
User entered 'No (N)'	System	17 Nov 2020 04:22:26

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:22:18', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c1ace06c-113b-48ba-b60d-b89ce45aee98'	System	17 Nov 2020 04:22:26
User entered 'None (1)'	System	17 Nov 2020 04:22:26

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:22:23', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c1ace06c-113b-48ba-b60d-b89ce45aee98'	System	17 Nov 2020 04:22:26
User entered '16 Nov 2020 20:22'	System	17 Nov 2020 04:22:26

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '16 Nov 2020 19:36'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '17 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 2'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:26:20', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd477e47f-1516-4071-8f54-ce0282c4203b'	System	18 Nov 2020 05:26:50
User entered 'Does not interfere with activity (2)'	System	18 Nov 2020 05:26:50

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:26:35', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd477e47f-1516-4071-8f54-ce0282c4203b' User entered 'No (N)'	System	18 Nov 2020 05:26:50
	System	18 Nov 2020 05:26:50

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:26:42', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd477e47f-1516-4071-8f54-ce0282c4203b' User entered 'No (N)'	System	18 Nov 2020 05:26:50
	System	18 Nov 2020 05:26:50

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:26:45', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd477e47f-1516-4071-8f54-ce0282c4203b' User entered 'None (1)'	System	18 Nov 2020 05:26:50
	System	18 Nov 2020 05:26:50

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:26:48', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'd477e47f-1516-4071-8f54-ce0282c4203b' User entered '17 Nov 2020 21:26'	System	18 Nov 2020 05:26:50
	System	18 Nov 2020 05:26:50

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '17 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '18 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 3'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:10:06', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e67ceb1c-54ae-4f9b-8937-df29bffb193'	System	19 Nov 2020 06:10:48
User entered 'Does not interfere with activity (2)'	System	19 Nov 2020 06:10:48

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:10:24', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e67ceb1c-54ae-4f9b-8937-df29bffb193'	System	19 Nov 2020 06:10:48
User entered 'No (N)'	System	19 Nov 2020 06:10:48

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:10:35', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e67ceb1c-54ae-4f9b-8937-df29bffb193'	System	19 Nov 2020 06:10:48
User entered 'No (N)'	System	19 Nov 2020 06:10:48

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:10:38', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e67ceb1c-54ae-4f9b-8937-df29bffb193'	System	19 Nov 2020 06:10:48
User entered 'None (1)'	System	19 Nov 2020 06:10:48

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:10:41', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e67ceb1c-54ae-4f9b-8937-df29bffb193'	System	19 Nov 2020 06:10:48
User entered '18 Nov 2020 22:10'	System	19 Nov 2020 06:10:48

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '18 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '19 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 4'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:05:40', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '77719d8b-2d99-4d9a-97e0-c0790f37bb21' User entered 'None (1)'	System	20 Nov 2020 06:05:57
	System	20 Nov 2020 06:05:57

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:05:45', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '77719d8b-2d99-4d9a-97e0-c0790f37bb21' User entered 'No (N)'	System	20 Nov 2020 06:05:57
	System	20 Nov 2020 06:05:57

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:05:48', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '77719d8b-2d99-4d9a-97e0-c0790f37bb21' User entered 'No (N)'	System	20 Nov 2020 06:05:57
	System	20 Nov 2020 06:05:57

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:05:50', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '77719d8b-2d99-4d9a-97e0-c0790f37bb21' User entered 'None (1)'	System	20 Nov 2020 06:05:57
	System	20 Nov 2020 06:05:57

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:05:53', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '77719d8b-2d99-4d9a-97e0-c0790f37bb21' User entered '19 Nov 2020 22:05'	System	20 Nov 2020 06:05:57
	System	20 Nov 2020 06:05:57

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '19 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '20 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 5'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:25', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c185ab5d-ee34-4d6c-bbd7-97dadfd3056c' User entered 'None (1)'	System	21 Nov 2020 08:01:37
	System	21 Nov 2020 08:01:37

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:28', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c185ab5d-ee34-4d6c-bbd7-97dadfd3056c' User entered 'No (N)'	System	21 Nov 2020 08:01:37
	System	21 Nov 2020 08:01:37

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:30', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c185ab5d-ee34-4d6c-bbd7-97dadfd3056c' User entered 'No (N)'	System	21 Nov 2020 08:01:37
	System	21 Nov 2020 08:01:37

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:32', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c185ab5d-ee34-4d6c-bbd7-97dadfd3056c' User entered 'None (1)'	System	21 Nov 2020 08:01:37
	System	21 Nov 2020 08:01:37

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:35', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c185ab5d-ee34-4d6c-bbd7-97dadfd3056c' User entered '21 Nov 2020 00:01'	System	21 Nov 2020 08:01:37
	System	21 Nov 2020 08:01:37

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '20 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '21 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 6'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:03:04', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '015e4d3a-5ea8-4451-8ed6-509916fe3248' User entered 'None (1)'	System	22 Nov 2020 08:03:15
	System	22 Nov 2020 08:03:15

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:03:07', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '015e4d3a-5ea8-4451-8ed6-509916fe3248' User entered 'No (N)'	System	22 Nov 2020 08:03:15
	System	22 Nov 2020 08:03:15

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:03:09', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '015e4d3a-5ea8-4451-8ed6-509916fe3248' User entered 'No (N)'	System	22 Nov 2020 08:03:15
	System	22 Nov 2020 08:03:15

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:03:10', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '015e4d3a-5ea8-4451-8ed6-509916fe3248' User entered 'None (1)'	System	22 Nov 2020 08:03:15
	System	22 Nov 2020 08:03:15

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:03:13', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '015e4d3a-5ea8-4451-8ed6-509916fe3248' User entered '22 Nov 2020 00:03'	System	22 Nov 2020 08:03:15
	System	22 Nov 2020 08:03:15

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '21 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '22 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 7'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:06:38', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'df307a94-3467-4581-b12d-f301059b832b' User entered 'None (1)'	System	23 Nov 2020 08:06:49
	System	23 Nov 2020 08:06:49

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:06:40', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'df307a94-3467-4581-b12d-f301059b832b' User entered 'No (N)'	System	23 Nov 2020 08:06:49
	System	23 Nov 2020 08:06:49

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:06:42', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'df307a94-3467-4581-b12d-f301059b832b' User entered 'No (N)'	System	23 Nov 2020 08:06:49
	System	23 Nov 2020 08:06:49

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:06:43', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'df307a94-3467-4581-b12d-f301059b832b' User entered 'None (1)'	System	23 Nov 2020 08:06:49
	System	23 Nov 2020 08:06:49

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:06:46', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'df307a94-3467-4581-b12d-f301059b832b' User entered '23 Nov 2020 00:06'	System	23 Nov 2020 08:06:49
	System	23 Nov 2020 08:06:49

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '22 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '23 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:31:39', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e5bc7565-52c1-4c73-a74f-465153e22961' User entered 'None (0)'	System	17 Nov 2020 04:19:18
	System	17 Nov 2020 04:19:18

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:31:44', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e5bc7565-52c1-4c73-a74f-465153e22961' User entered 'None (0)'	System	17 Nov 2020 04:19:18
	System	17 Nov 2020 04:19:18

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:31:47', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e5bc7565-52c1-4c73-a74f-465153e22961' User entered 'None (0)'	System	17 Nov 2020 04:19:18
	System	17 Nov 2020 04:19:18

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:31:51', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e5bc7565-52c1-4c73-a74f-465153e22961' User entered 'None (0)'	System	17 Nov 2020 04:19:18
	System	17 Nov 2020 04:19:18

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:31:53', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e5bc7565-52c1-4c73-a74f-465153e22961' User entered 'None (0)'	System	17 Nov 2020 04:19:18
	System	17 Nov 2020 04:19:18

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:32:13', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e5bc7565-52c1-4c73-a74f-465153e22961' User entered 'None (0)'	System	17 Nov 2020 04:19:18
	System	17 Nov 2020 04:19:18

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:32:24', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e5bc7565-52c1-4c73-a74f-465153e22961' User entered 'No (N)'	System	17 Nov 2020 04:19:18
	System	17 Nov 2020 04:19:18

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T16:32:29', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e5bc7565-52c1-4c73-a74f-465153e22961' User entered '16 Nov 2020 16:32'	System	17 Nov 2020 04:19:18
	System	17 Nov 2020 04:19:18

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '16 Nov 2020 16:11'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '16 Nov 2020 18:41'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 1, after vaccination (at home)'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:22:43', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5e7268d1-17c5-4a45-a42a-03862ac309bc' User entered 'None (0)'	System	17 Nov 2020 04:23:56
	System	17 Nov 2020 04:23:56

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:22:50', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5e7268d1-17c5-4a45-a42a-03862ac309bc' User entered 'None (0)'	System	17 Nov 2020 04:23:56
	System	17 Nov 2020 04:23:56

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:22:55', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5e7268d1-17c5-4a45-a42a-03862ac309bc' User entered 'None (0)'	System	17 Nov 2020 04:23:56
	System	17 Nov 2020 04:23:56

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:22:58', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5e7268d1-17c5-4a45-a42a-03862ac309bc' User entered 'None (0)'	System	17 Nov 2020 04:23:56
	System	17 Nov 2020 04:23:56

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:23:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5e7268d1-17c5-4a45-a42a-03862ac309bc' User entered 'None (0)'	System	17 Nov 2020 04:23:56
	System	17 Nov 2020 04:23:56

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:23:04', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5e7268d1-17c5-4a45-a42a-03862ac309bc' User entered 'None (0)'	System	17 Nov 2020 04:23:56
	System	17 Nov 2020 04:23:56

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:23:32', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5e7268d1-17c5-4a45-a42a-03862ac309bc' User entered 'No (N)'	System	17 Nov 2020 04:23:56
	System	17 Nov 2020 04:23:56

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-16T20:23:52', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5e7268d1-17c5-4a45-a42a-03862ac309bc' User entered '16 Nov 2020 20:23'	System	17 Nov 2020 04:23:56
	System	17 Nov 2020 04:23:56

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '16 Nov 2020 19:36'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '17 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 2'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:26:52', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e20be24b-9ece-4ace-9d81-c46f13792f68' User entered 'None (0)'	System	18 Nov 2020 05:27:19
	System	18 Nov 2020 05:27:19

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:26:58', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e20be24b-9ece-4ace-9d81-c46f13792f68'	System	18 Nov 2020 05:27:19
User entered 'No interference with activity (1)'	System	18 Nov 2020 05:27:19

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:27:02', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e20be24b-9ece-4ace-9d81-c46f13792f68' User entered 'None (0)'	System	18 Nov 2020 05:27:19
	System	18 Nov 2020 05:27:19

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:27:04', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e20be24b-9ece-4ace-9d81-c46f13792f68' User entered 'None (0)'	System	18 Nov 2020 05:27:19
	System	18 Nov 2020 05:27:19

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:27:06', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e20be24b-9ece-4ace-9d81-c46f13792f68' User entered 'None (0)'	System	18 Nov 2020 05:27:19
	System	18 Nov 2020 05:27:19

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:27:08', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e20be24b-9ece-4ace-9d81-c46f13792f68' User entered 'None (0)'	System	18 Nov 2020 05:27:19
	System	18 Nov 2020 05:27:19

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:27:11', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e20be24b-9ece-4ace-9d81-c46f13792f68' User entered 'No (N)'	System	18 Nov 2020 05:27:19
	System	18 Nov 2020 05:27:19

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-17T21:27:17', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e20be24b-9ece-4ace-9d81-c46f13792f68' User entered '17 Nov 2020 21:27'	System	18 Nov 2020 05:27:19
	System	18 Nov 2020 05:27:19

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '17 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '18 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 3'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:10:53', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '93b5893d-e922-4e5a-8c0c-8bfbb47a9526' User entered 'None (0)'	System	19 Nov 2020 06:11:15
	System	19 Nov 2020 06:11:15

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:10:55', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '93b5893d-e922-4e5a-8c0c-8bfbb47a9526'	System	19 Nov 2020 06:11:15
User entered 'No interference with activity (1)'	System	19 Nov 2020 06:11:15

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:10:58', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '93b5893d-e922-4e5a-8c0c-8bfbb47a9526' User entered 'None (0)'	System	19 Nov 2020 06:11:15
	System	19 Nov 2020 06:11:15

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:11:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '93b5893d-e922-4e5a-8c0c-8bfbb47a9526' User entered 'None (0)'	System	19 Nov 2020 06:11:15
	System	19 Nov 2020 06:11:15

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:11:02', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '93b5893d-e922-4e5a-8c0c-8bfbb47a9526' User entered 'None (0)'	System	19 Nov 2020 06:11:15
	System	19 Nov 2020 06:11:15

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:11:04', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '93b5893d-e922-4e5a-8c0c-8bfbb47a9526' User entered 'None (0)'	System	19 Nov 2020 06:11:15
	System	19 Nov 2020 06:11:15

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:11:09', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '93b5893d-e922-4e5a-8c0c-8bfbb47a9526' User entered 'No (N)'	System	19 Nov 2020 06:11:15
	System	19 Nov 2020 06:11:15

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-18T22:11:12', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '93b5893d-e922-4e5a-8c0c-8bfbb47a9526' User entered '18 Nov 2020 22:11'	System	19 Nov 2020 06:11:15
	System	19 Nov 2020 06:11:15

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '18 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '19 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 4'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:05:58', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '398c8ce7-22b9-48d0-9f2e-b10acdaf5029' User entered 'None (0)'	System	20 Nov 2020 06:06:22
	System	20 Nov 2020 06:06:22

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:06:02', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '398c8ce7-22b9-48d0-9f2e-b10acdaf5029' User entered 'None (0)'	System	20 Nov 2020 06:06:22
	System	20 Nov 2020 06:06:22

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:06:06', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '398c8ce7-22b9-48d0-9f2e-b10acdaf5029' User entered 'None (0)'	System	20 Nov 2020 06:06:22
	System	20 Nov 2020 06:06:22

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:06:09', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '398c8ce7-22b9-48d0-9f2e-b10acdaf5029' User entered 'None (0)'	System	20 Nov 2020 06:06:22
	System	20 Nov 2020 06:06:22

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:06:11', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '398c8ce7-22b9-48d0-9f2e-b10acdaf5029' User entered 'None (0)'	System	20 Nov 2020 06:06:22
	System	20 Nov 2020 06:06:22

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:06:13', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '398c8ce7-22b9-48d0-9f2e-b10acdaf5029' User entered 'None (0)'	System	20 Nov 2020 06:06:22
	System	20 Nov 2020 06:06:22

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:06:15', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '398c8ce7-22b9-48d0-9f2e-b10acdaf5029' User entered 'No (N)'	System	20 Nov 2020 06:06:22
	System	20 Nov 2020 06:06:22

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-19T22:06:17', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '398c8ce7-22b9-48d0-9f2e-b10acdaf5029' User entered '19 Nov 2020 22:06'	System	20 Nov 2020 06:06:22
	System	20 Nov 2020 06:06:22

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '19 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '20 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 5'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:39', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'ca08a49e-3586-4a36-b6cd-da863f2c09f6' User entered 'None (0)'	System	21 Nov 2020 08:01:55
	System	21 Nov 2020 08:01:55

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:41', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'ca08a49e-3586-4a36-b6cd-da863f2c09f6'	System	21 Nov 2020 08:01:55
User entered 'No interference with activity (1)'	System	21 Nov 2020 08:01:55

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:43', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'ca08a49e-3586-4a36-b6cd-da863f2c09f6'	System	21 Nov 2020 08:01:55
User entered 'None (0)'	System	21 Nov 2020 08:01:55

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:44', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'ca08a49e-3586-4a36-b6cd-da863f2c09f6' User entered 'None (0)'	System	21 Nov 2020 08:01:55
	System	21 Nov 2020 08:01:55

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:46', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'ca08a49e-3586-4a36-b6cd-da863f2c09f6' User entered 'None (0)'	System	21 Nov 2020 08:01:55
	System	21 Nov 2020 08:01:55

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:48', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'ca08a49e-3586-4a36-b6cd-da863f2c09f6' User entered 'None (0)'	System	21 Nov 2020 08:01:55
	System	21 Nov 2020 08:01:55

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:51', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'ca08a49e-3586-4a36-b6cd-da863f2c09f6' User entered 'No (N)'	System	21 Nov 2020 08:01:55
	System	21 Nov 2020 08:01:55

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-21T00:01:53', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'ca08a49e-3586-4a36-b6cd-da863f2c09f6' User entered '21 Nov 2020 00:01'	System	21 Nov 2020 08:01:55
	System	21 Nov 2020 08:01:55

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '20 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '21 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 6'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:03:17', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c8a776c2-1aa0-446e-9866-f3df5629dfbc' User entered 'None (0)'	System	22 Nov 2020 08:03:38
	System	22 Nov 2020 08:03:38

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:03:21', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c8a776c2-1aa0-446e-9866-f3df5629dfbc'	System	22 Nov 2020 08:03:38
User entered 'No interference with activity (1)'	System	22 Nov 2020 08:03:38

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:03:23', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c8a776c2-1aa0-446e-9866-f3df5629dfbc' User entered 'None (0)'	System	22 Nov 2020 08:03:38
	System	22 Nov 2020 08:03:38

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:03:27', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c8a776c2-1aa0-446e-9866-f3df5629dfbc' User entered 'None (0)'	System	22 Nov 2020 08:03:38
	System	22 Nov 2020 08:03:38

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:03:28', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c8a776c2-1aa0-446e-9866-f3df5629dfbc' User entered 'None (0)'	System	22 Nov 2020 08:03:38
	System	22 Nov 2020 08:03:38

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:03:31', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c8a776c2-1aa0-446e-9866-f3df5629dfbc' User entered 'None (0)'	System	22 Nov 2020 08:03:38
	System	22 Nov 2020 08:03:38

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:03:32', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c8a776c2-1aa0-446e-9866-f3df5629dfbc' User entered 'No (N)'	System	22 Nov 2020 08:03:38
	System	22 Nov 2020 08:03:38

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-22T00:03:35', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c8a776c2-1aa0-446e-9866-f3df5629dfbc' User entered '22 Nov 2020 00:03'	System	22 Nov 2020 08:03:38
	System	22 Nov 2020 08:03:38

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '21 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '22 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
Data entry locked.	System	17 Nov 2020 00:18:35
User entered 'Day 7'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:06:54', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'a9d321c0-0ad1-41bb-b756-ba117f7b934d' User entered 'None (0)'	System	23 Nov 2020 08:07:12
	System	23 Nov 2020 08:07:12

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:06:56', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'a9d321c0-0ad1-41bb-b756-ba117f7b934d' User entered 'None (0)'	System	23 Nov 2020 08:07:12
	System	23 Nov 2020 08:07:12

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:06:58', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'a9d321c0-0ad1-41bb-b756-ba117f7b934d' User entered 'None (0)'	System	23 Nov 2020 08:07:12
	System	23 Nov 2020 08:07:12

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:06:59', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'a9d321c0-0ad1-41bb-b756-ba117f7b934d' User entered 'None (0)'	System	23 Nov 2020 08:07:12
	System	23 Nov 2020 08:07:12

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:07:01', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'a9d321c0-0ad1-41bb-b756-ba117f7b934d' User entered 'None (0)'	System	23 Nov 2020 08:07:12
	System	23 Nov 2020 08:07:12

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:07:02', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'a9d321c0-0ad1-41bb-b756-ba117f7b934d' User entered 'None (0)'	System	23 Nov 2020 08:07:12
	System	23 Nov 2020 08:07:12

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

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 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:07:05', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'a9d321c0-0ad1-41bb-b756-ba117f7b934d' User entered 'No (N)'	System	23 Nov 2020 08:07:12
	System	23 Nov 2020 08:07:12

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-11-23T00:07:08', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'a9d321c0-0ad1-41bb-b756-ba117f7b934d' User entered '23 Nov 2020 00:07'	System	23 Nov 2020 08:07:12
	System	23 Nov 2020 08:07:12

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '22 Nov 2020 12:00'	System	17 Nov 2020 00:18:35

US3162290

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:08:53
User entered '23 Nov 2020 11:59'	System	17 Nov 2020 00:18:35

US3162290

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 17:35:19

US3162290

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '24 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 17:35:19

US3162290

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Nov 2020 17:35:19

US3162290

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 17:35:19

US3162290

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 17:35:26

US3162290

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'I'	System	25 Nov 2020 17:35:26

US3162290

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	02 Dec 2020 19:15:08

US3162290

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '30 Nov 2020'	Tiffany Williams (b) (4)	02 Dec 2020 19:15:08
	(b) (4)	

US3162290

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	02 Dec 2020 19:15:08
	(b) (4)	

US3162290

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Tiffany Williams (b) (4) (b) (4)	02 Dec 2020 19:15:08

US3162290

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	02 Dec 2020 19:15:18

US3162290

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'I'	System	02 Dec 2020 19:15:18

US3162290

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	08 Dec 2020 19:57:34
	(b) (4)	

US3162290

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '7 Dec 2020'	Tiffany Williams (b) (4)	08 Dec 2020 19:57:34
	(b) (4)	

US3162290

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	08 Dec 2020 19:57:34

US3162290

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Tiffany Williams (b) (4) (b) (4)	08 Dec 2020 19:57:34

US3162290

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	08 Dec 2020 19:57:41

US3162290

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'I'	System	08 Dec 2020 19:57:41

US3162290

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	21 Dec 2020 19:19:51
	(b) (4)	

US3162290

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '18 Dec 2020'	Tiffany Williams (b) (4)	21 Dec 2020 19:19:51
	(b) (4)	

US3162290

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4)	21 Dec 2020 19:19:51
	(b) (4)	

US3162290

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'VISIT3'	System	21 Dec 2020 19:19:51

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	21 Dec 2020 19:21:34

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '18 Dec 2020'	Tiffany Williams (b) (4)	21 Dec 2020 19:21:34
	(b) (4)	

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '15:57'	Tiffany Williams (b) (4)	21 Dec 2020 19:21:34
	(b) (4)	

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered '18 Dec 2020 15:57'	System	21 Dec 2020 19:21:34

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '98.4' F	Tiffany Williams (b) (4)	21 Dec 2020 19:21:34
	(b) (4)	

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	21 Dec 2020 19:21:34

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	21 Dec 2020 19:21:34
	(b) (4)	

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '86'	Tiffany Williams (b) (4)	21 Dec 2020 19:21:34
	(b) (4)	

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'bpm'	System	21 Dec 2020 19:21:34

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '12'	Tiffany Williams (b) (4) (b) (4)	21 Dec 2020 19:21:34

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'breaths/min'	System	21 Dec 2020 19:21:34

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '132'	Tiffany Williams (b) (4) (b) (4)	21 Dec 2020 19:21:34

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'mmHg'	System	21 Dec 2020 19:21:34

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '87'	Tiffany Williams (b) (4) (b) (4)	21 Dec 2020 19:21:34

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'mmHg'	System	21 Dec 2020 19:21:34

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04

US3162290

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04

US3162290

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	21 Dec 2020 19:21:46

US3162290

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	21 Dec 2020 19:21:46
	(b) (4)	

US3162290

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	21 Dec 2020 19:22:10

US3162290

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '18 Dec 2020'	Tiffany Williams (b) (4) (b) (4)	21 Dec 2020 19:22:10

US3162290

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '16:07'	Tiffany Williams (b) (4) (b) (4)	21 Dec 2020 19:22:10

US3162290

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered '18 Dec 2020 16:07'	System	21 Dec 2020 19:22:10

US3162290

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	21 Dec 2020 19:22:16

US3162290

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'I'	System	21 Dec 2020 19:22:16

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-12-16T10:52:11', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '02625118-d410-4e00-94ee-60be9f55742e' User entered 'No (N)'	System	16 Dec 2020 18:53:17
	System	16 Dec 2020 18:53:17

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-12-16T10:52:48', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '02625118-d410-4e00-94ee-60be9f55742e' User entered 'Yes (Y)'	System	16 Dec 2020 18:53:17
	System	16 Dec 2020 18:53:17

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Please 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-12-16T10:52:53', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '02625118-d410-4e00-94ee-60be9f55742e'	System	16 Dec 2020 18:53:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Dec 2020 18:53:17

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-12-16T10:53:06', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '02625118-d410-4e00-94ee-60be9f55742e' User entered '16 Dec 2020 10:53:06'	System	16 Dec 2020 18:53:17
	System	16 Dec 2020 18:53:17

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-12-23T13:36:36', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '1570a03d-9d3a-4ad0-9700-0671f95538e5' User entered 'No (N)'	System	23 Dec 2020 21:38:00
	System	23 Dec 2020 21:38:00

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-12-23T13:37:53', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '1570a03d-9d3a-4ad0-9700-0671f95538e5' User entered 'No (N)'	System	23 Dec 2020 21:38:00
	System	23 Dec 2020 21:38:00

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-12-23T13:37:56', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '1570a03d-9d3a-4ad0-9700-0671f95538e5' User entered '23 Dec 2020 13:37:56'	System	23 Dec 2020 21:38:00
	System	23 Dec 2020 21:38:00

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-12-30T00:06:07', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c60e4c74-8cf7-462b-aa04-fd0465db1897'	System	30 Dec 2020 08:06:37
User entered 'No (N)'	System	30 Dec 2020 08:06:37

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-12-30T00:06:22', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c60e4c74-8cf7-462b-aa04-fd0465db1897'	System	30 Dec 2020 08:06:37
User entered 'No (N)'	System	30 Dec 2020 08:06:37

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2020-12-30T00:06:35', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c60e4c74-8cf7-462b-aa04-fd0465db1897' User entered '30 Dec 2020 00:06:35'	System	30 Dec 2020 08:06:37
	System	30 Dec 2020 08:06:37

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-01-07T19:58:45', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c7a88721-b9d2-4068-b5eb-2097bed27504'	System	08 Jan 2021 03:59:11
User entered 'No (N)'	System	08 Jan 2021 03:59:11

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-01-07T19:59:03', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c7a88721-b9d2-4068-b5eb-2097bed27504'	System	08 Jan 2021 03:59:11
User entered 'No (N)'	System	08 Jan 2021 03:59:11

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-01-07T19:59:09', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c7a88721-b9d2-4068-b5eb-2097bed27504'	System	08 Jan 2021 03:59:11
User entered '07 Jan 2021 19:59:09'	System	08 Jan 2021 03:59:11

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-01-13T00:26:12', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e80ac547-b476-4dc0-ac3c-438a4341087e' User entered 'No (N)'	System	13 Jan 2021 08:26:29
	System	13 Jan 2021 08:26:29

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-01-13T00:26:16', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e80ac547-b476-4dc0-ac3c-438a4341087e' User entered 'No (N)'	System	13 Jan 2021 08:26:29

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-01-13T00:26:20', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'e80ac547-b476-4dc0-ac3c-438a4341087e' User entered '13 Jan 2021 00:26:20'	System	13 Jan 2021 08:26:29
	System	13 Jan 2021 08:26:29

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-01-20T09:52:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '1d4b26f8-ca54-4c06-8878-a263220aafdd' User entered 'No (N)'	System	20 Jan 2021 17:53:00

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-01-20T09:52:53', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '1d4b26f8-ca54-4c06-8878-a263220aafdd' User entered 'No (N)'	System	20 Jan 2021 17:53:00

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-01-20T09:52:57', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '1d4b26f8-ca54-4c06-8878-a263220aafdd' User entered '20 Jan 2021 09:52:57'	System	20 Jan 2021 17:53:00
	System	20 Jan 2021 17:53:00

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-01-27T00:04:17', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '2aa820b8-d1d9-499b-829f-1e40a8b68445' User entered 'No (N)'	System	27 Jan 2021 08:04:31
	System	27 Jan 2021 08:04:31

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-01-27T00:04:24', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '2aa820b8-d1d9-499b-829f-1e40a8b68445'	System	27 Jan 2021 08:04:31
User entered 'No (N)'	System	27 Jan 2021 08:04:31

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-01-27T00:04:28', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '2aa820b8-d1d9-499b-829f-1e40a8b68445' User entered '27 Jan 2021 00:04:28'	System	27 Jan 2021 08:04:31
	System	27 Jan 2021 08:04:31

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-03T04:17:14', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'de86fd24-7375-4fcc-829f-fbc7f30cb023' User entered 'No (N)'	System	03 Feb 2021 12:18:44
	System	03 Feb 2021 12:18:44

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-03T04:18:32', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'de86fd24-7375-4fcc-829f-fbc7f30cb023' User entered 'No (N)'	System	03 Feb 2021 12:18:44

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-03T04:18:39', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'de86fd24-7375-4fcc-829f-fbc7f30cb023' User entered '03 Feb 2021 04:18:39'	System	03 Feb 2021 12:18:44
	System	03 Feb 2021 12:18:44

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:44:21', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989'	System	11 Feb 2021 03:50:53
User entered 'Yes (Y)'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:44:26', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered 'No (N)'	System	11 Feb 2021 03:50:53
	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:44:40', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989'	System	11 Feb 2021 03:50:53
User entered 'Yes (Y)'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '0'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '0'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '0'	System	11 Feb 2021 03:50:53
	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '0'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '0'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '1'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '0'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '0'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989'	System	11 Feb 2021 03:50:53
User entered '1'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '0'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '0'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '0'	System	11 Feb 2021 03:50:53
	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '0'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '1'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '0'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '0'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:19', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '0'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Please 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:49:04', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989'	System	11 Feb 2021 03:50:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:46:48', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989'	System	11 Feb 2021 03:50:53
User entered 'No (N)'	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-10T19:49:12', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '31a49f84-f1f1-4b5c-b75d-44488231b989' User entered '10 Feb 2021 19:49:12'	System	11 Feb 2021 03:50:53
	System	11 Feb 2021 03:50:53

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-17T14:25:35', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '2479ec62-3843-49f7-acfd-e081e7c6879b' User entered 'No (N)'	System	17 Feb 2021 22:25:44
	System	17 Feb 2021 22:25:44

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-17T14:25:38', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '2479ec62-3843-49f7-acfd-e081e7c6879b' User entered 'No (N)'	System	17 Feb 2021 22:25:44
	System	17 Feb 2021 22:25:44

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-17T14:25:41', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '2479ec62-3843-49f7-acfd-e081e7c6879b' User entered '17 Feb 2021 14:25:41'	System	17 Feb 2021 22:25:44
	System	17 Feb 2021 22:25:44

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-24T07:54:34-08:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'df6b5e66-b71a-4124-aa9c-2179c0c2d92b' User entered 'No (N)'	System	24 Feb 2021 15:54:48

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-24T07:54:40-08:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'df6b5e66-b71a-4124-aa9c-2179c0c2d92b' User entered 'No (N)'	System	24 Feb 2021 15:54:48
	System	24 Feb 2021 15:54:48

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-02-24T07:54:45-08:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'df6b5e66-b71a-4124-aa9c-2179c0c2d92b'	System	24 Feb 2021 15:54:48
User entered '24 Feb 2021 15:54:45'	System	24 Feb 2021 15:54:48

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-03T18:01:07-08:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '7036e605-2083-4a0a-a4c5-6fcc409a1349'	System	04 Mar 2021 02:04:28
User entered 'No (N)'	System	04 Mar 2021 02:04:28

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-03T18:01:12-08:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '7036e605-2083-4a0a-a4c5-6fcc409a1349'	System	04 Mar 2021 02:04:28
User entered 'No (N)'	System	04 Mar 2021 02:04:28

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-03T18:01:15-08:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '7036e605-2083-4a0a-a4c5-6fcc409a1349' User entered '03 Mar 2021 18:01:15'	System	04 Mar 2021 02:04:28
	System	04 Mar 2021 02:04:28

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-10T12:04:06-08:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c301545d-1064-4484-a8c8-6f1faccb05b7'	System	10 Mar 2021 20:04:48
User entered 'Yes (Y)'	System	10 Mar 2021 20:04:48

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-10T12:04:09-08:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c301545d-1064-4484-a8c8-6f1faccb05b7'	System	10 Mar 2021 20:04:48
User entered 'No (N)'	System	10 Mar 2021 20:04:48

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-10T12:04:14-08:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c301545d-1064-4484-a8c8-6f1facb05b7'	System	10 Mar 2021 20:04:48
User entered 'No (N)'	System	10 Mar 2021 20:04:48

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-10T12:04:23-08:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c301545d-1064-4484-a8c8-6f1faccb05b7'	System	10 Mar 2021 20:04:48
User entered 'Yes (Y)'	System	10 Mar 2021 20:04:48

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Please 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-10T12:04:27-08:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c301545d-1064-4484-a8c8-6f1faccb05b7'	System	10 Mar 2021 20:04:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Mar 2021 20:04:48

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-10T12:04:35-08:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c301545d-1064-4484-a8c8-6f1faccb05b7'	System	10 Mar 2021 20:04:48
User entered '10 Mar 2021 12:04:35'	System	10 Mar 2021 20:04:48

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-17T14:52:25-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'abe3e826-b365-4ad1-b159-e109f2b8a1b3' User entered 'Yes (Y)'	System	17 Mar 2021 21:53:13
	System	17 Mar 2021 21:53:13

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-17T14:52:29-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'abe3e826-b365-4ad1-b159-e109f2b8a1b3'	System	17 Mar 2021 21:53:13
User entered 'No (N)'	System	17 Mar 2021 21:53:13

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-17T14:52:33-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'abe3e826-b365-4ad1-b159-e109f2b8a1b3' User entered 'No (N)'	System	17 Mar 2021 21:53:13
	System	17 Mar 2021 21:53:13

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-17T14:52:43-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'abe3e826-b365-4ad1-b159-e109f2b8a1b3'	System	17 Mar 2021 21:53:13
User entered 'No (N)'	System	17 Mar 2021 21:53:13

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-17T14:53:09-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'abe3e826-b365-4ad1-b159-e109f2b8a1b3' User entered '17 Mar 2021 14:53:09'	System	17 Mar 2021 21:53:13
	System	17 Mar 2021 21:53:13

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-24T13:00:33-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5c219be4-e11d-4e52-b8a9-748cbece02af'	System	24 Mar 2021 20:00:50
User entered 'No (N)'	System	24 Mar 2021 20:00:50

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-24T13:00:40-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5c219be4-e11d-4e52-b8a9-748cbece02af'	System	24 Mar 2021 20:00:50
User entered 'No (N)'	System	24 Mar 2021 20:00:50

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-24T13:00:47-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '5c219be4-e11d-4e52-b8a9-748cbece02af' User entered '24 Mar 2021 13:00:47'	System	24 Mar 2021 20:00:50
	System	24 Mar 2021 20:00:50

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-31T20:26:18-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c1b1e908-0357-4774-8865-d846abd78ce9'	System	01 Apr 2021 03:26:30
User entered 'No (N)'	System	01 Apr 2021 03:26:30

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-31T20:26:23-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c1b1e908-0357-4774-8865-d846abd78ce9'	System	01 Apr 2021 03:26:30
User entered 'No (N)'	System	01 Apr 2021 03:26:30

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-31T20:26:27-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'c1b1e908-0357-4774-8865-d846abd78ce9' User entered '31 Mar 2021 20:26:27'	System	01 Apr 2021 03:26:30
	System	01 Apr 2021 03:26:30

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-04-07T08:54:50-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '6294a67e-977e-415f-8a07-dd9f0f9715d4' User entered 'No (N)'	System	07 Apr 2021 15:55:06
	System	07 Apr 2021 15:55:06

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-04-07T08:54:55-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '6294a67e-977e-415f-8a07-dd9f0f9715d4' User entered 'No (N)'	System	07 Apr 2021 15:55:06
	System	07 Apr 2021 15:55:06

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-04-07T08:54:59-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '6294a67e-977e-415f-8a07-dd9f0f9715d4'	System	07 Apr 2021 15:55:06
User entered '07 Apr 2021 08:54:59'	System	07 Apr 2021 15:55:06

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-04-14T00:36:33-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '8ff78b21-a1b5-4314-a4f7-08ca5d8de759'	System	14 Apr 2021 07:36:43
User entered 'No (N)'	System	14 Apr 2021 07:36:43

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-04-14T00:36:36-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '8ff78b21-a1b5-4314-a4f7-08ca5d8de759'	System	14 Apr 2021 07:36:43
User entered 'No (N)'	System	14 Apr 2021 07:36:43

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-04-14T00:36:39-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '8ff78b21-a1b5-4314-a4f7-08ca5d8de759'	System	14 Apr 2021 07:36:43
User entered '14 Apr 2021 00:36:39'	System	14 Apr 2021 07:36:43

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-04-21T04:56:05-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'b5cfa327-fb3f-4ce6-8663-346ce4c6e860' User entered 'No (N)'	System	21 Apr 2021 11:56:14

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-04-21T04:56:08-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'b5cfa327-fb3f-4ce6-8663-346ce4c6e860' User entered 'No (N)'	System	21 Apr 2021 11:56:14

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-04-21T04:56:11-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: 'b5cfa327-fb3f-4ce6-8663-346ce4c6e860'	System	21 Apr 2021 11:56:14
User entered '21 Apr 2021 04:56:11'	System	21 Apr 2021 11:56:14

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-04-28T05:02:13-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '95897fea-0a5c-47cf-af3d-da3ba6644f64'	System	28 Apr 2021 23:13:54
User entered 'No (N)'	System	28 Apr 2021 23:13:54

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

Have you been exposed to someone with 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 (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-04-28T05:02:16-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '95897fea-0a5c-47cf-af3d-da3ba6644f64' User entered 'No (N)'	System	28 Apr 2021 23:13:54

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-04-28T05:02:22-07:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '95897fea-0a5c-47cf-af3d-da3ba6644f64'	System	28 Apr 2021 23:13:54
User entered '28 Apr 2021 05:02:22'	System	28 Apr 2021 23:13:54

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '23 Nov 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '27 Nov 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '30 Nov 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '04 Dec 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '07 Dec 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '11 Dec 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '14 Dec 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '18 Dec 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '21 Dec 2022 00:01'	System	20 Nov 2020 13:09:56

US3162290

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:09:56
Amendment Manager: User entered '25 Dec 2022 23:59'	System	20 Nov 2020 13:09:56

US3162290

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:32:14

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 21:32:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-01T17:12:06-08:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '48ce9e12-3c58-48f6-a60c-2d1a1fa59d26'	System	02 Mar 2021 01:12:15
User entered 'No (N)'	System	02 Mar 2021 01:12:15

US3162290

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:32:14

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:32:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8134915D-2A17-4D2E-A841-DEFAC796C4A2)', Time: '2021-03-01T17:12:13-08:00', User OID: 'PatientReportedOutcome (US3162290)', ODM File OID: '48ce9e12-3c58-48f6-a60c-2d1a1fa59d26'	System	02 Mar 2021 01:12:15
User entered '02 Mar 2021 01:12:13'	System	02 Mar 2021 01:12:15

US3162290

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	26 Jan 2021 19:53:54
	(b) (4)	

US3162290

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '10 Jan 2021'	Tiffany Williams (b) (4)	26 Jan 2021 19:53:54
	(b) (4)	

US3162290

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	26 Jan 2021 19:53:54

US3162290

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Tiffany Williams (b) (4) (b) (4)	26 Jan 2021 19:53:54

US3162290

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	26 Jan 2021 19:54:00

US3162290

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:32:04
User entered 'I'	System	26 Jan 2021 19:54:00

US3162290

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:41:46

US3162290

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '17 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:41:46

US3162290

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:41:46

US3162290

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered empty.	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:41:46

US3162290

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:41:52

US3162290

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:18
User entered 'I'	System	18 Feb 2021 20:41:52

US3162290

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	17 Mar 2021 17:18:32

US3162290

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '16 Mar 2021'	Tiffany Williams (b) (4) (b) (4)	17 Mar 2021 17:18:32

US3162290

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	17 Mar 2021 17:18:32

US3162290

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered empty.	Tiffany Williams (b) (4) (b) (4)	17 Mar 2021 17:18:32

US3162290

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	17 Mar 2021 17:18:43

US3162290

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:18
User entered 'I'	System	17 Mar 2021 17:18:43

US3162290

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 21:05:42

US3162290

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '15 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 21:05:42

US3162290

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Apr 2021 21:05:42

US3162290

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 21:05:42

US3162290

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 21:05:59

US3162290

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:14

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 21:05:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:14

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '2 Nov 2020'	Judith Kirstein (b) (4)	03 Nov 2020 06:26:48
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:14

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '09:00'	Judith Kirstein (b) (4)	03 Nov 2020 06:26:48
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:14

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '2 Nov 2020 09:00'	System	03 Nov 2020 06:26:48

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:14

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'Safety Call (Safety Call)'	Judith Kirstein (b) (4)	03 Nov 2020 06:26:48
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:14

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:26:48

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 1 (Day 1)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '26 Oct 2020'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User closed query 'Per CDM: it appears that both O2 Saturation and Temperature were not collected for Day 1-7. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4)	15 Feb 2021 21:43:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:59:16
Query 'Per CDM: it appears that both O2 Saturation and Temperature were not collected for Day 1-7. If not collected, please consider recording these as Not Done.' answered with 'Done' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:58:21
User opened query 'Per CDM: it appears that both O2 Saturation and Temperature were not collected for Day 1-7. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 09:09:22
Query 'Per CDM: it appears that Lines from 1-7 are missing O2 Saturation and Temperature. If not collected, please consider recording as Not Done' canceled (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 09:09:13
User opened query 'Per CDM: it appears that Lines from 1-7 are missing O2 Saturation and Temperature. If not collected, please consider recording as Not Done' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 08:55:51
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	03 Feb 2021 01:59:16
User entered empty.	System	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:59:16
Query 'Per CDM: it appears that Lines from 1-7 are missing O2 Saturation and Temperature. If not collected, please consider recording as Not Done' canceled (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 09:05:28
User opened query 'Per CDM: it appears that Lines from 1-7 are missing O2 Saturation and Temperature. If not collected, please consider recording as Not Done' (Site from DM).		07 Jan 2021 08:55:58
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	03 Nov 2020 06:30:29
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:30:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	03 Nov 2020 06:30:29
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 2 (Day 2)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '27 Oct 2020'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User closed query 'Per CDM: it appears that Lines from 1-7 are missing O2 Saturation and Temperature. If not collected, please consider recording as Not Done' (Site from DM).		15 Feb 2021 21:44:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
Query 'Per CDM: it appears that Lines from 1-7 are missing O2 Saturation and Temperature. If not collected, please consider recording as Not Done' answered with 'corrected' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:59:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:59:16
User opened query 'Per CDM: it appears that Lines from 1-7 are missing O2 Saturation and Temperature. If not collected, please consider recording as Not Done' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 08:54:39
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	03 Feb 2021 01:59:16
User entered empty.	System	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User closed query 'Per CDM: it appears that Lines from 1-7 are missing O2 Saturation and Temperature. If not collected, please consider recording as Not Done' (Site from DM).		15 Feb 2021 21:44:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
Query 'Per CDM: it appears that Lines from 1-7 are missing O2 Saturation and Temperature. If not collected, please consider recording as Not Done' answered with 'corrected' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:59:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:59:16
User opened query 'Per CDM: it appears that Lines from 1-7 are missing O2 Saturation and Temperature. If not collected, please consider recording as Not Done' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 08:54:47
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:34:06

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 3 (Day 3)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '28 Oct 2020'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:59:16
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	03 Feb 2021 01:59:16
User entered empty.	System	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:59:16
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:37:47

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 4 (Day 4)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '29 Oct 2020'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	03 Nov 2020 06:40:38
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:59:16
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	03 Feb 2021 01:59:16
User entered empty.	System	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:59:16
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	03 Nov 2020 06:40:38
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	03 Nov 2020 06:40:38
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:40:38

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 5 (Day 5)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '30 Oct 2020'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	03 Nov 2020 06:42:50
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:59:16
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	03 Feb 2021 01:59:16
User entered empty.	System	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:59:16
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:42:50

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 6 (Day 6)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '31 Oct 2020'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	03 Nov 2020 06:44:59
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:59:16
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	03 Feb 2021 01:59:16
User entered empty.	System	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:59:16
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:44:59

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 7 (Day 7)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '1 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	03 Nov 2020 06:48:14
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:59:16
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	03 Feb 2021 01:59:16
User entered empty.	System	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 01:59:16
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	03 Nov 2020 06:48:14
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	03 Nov 2020 06:48:14
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:48:14

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 8 (Day 8)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '2 Nov 2020'	Judith Kirstein (b) (4)	03 Nov 2020 06:51:29
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '99'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '98.2' F	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	03 Nov 2020 06:51:29
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:51:29

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '3 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '98'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '98.2' F	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 01:39:45

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 10 (Day 10)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '4 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '99'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '96.2' F	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	05 Nov 2020 20:03:02
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:03:02

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 11 (Day 11)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '5 Nov 2020'	Judith Kirstein (b) (4)	05 Nov 2020 20:05:01
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	05 Nov 2020 20:05:01
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '99'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '96.5' F	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	05 Nov 2020 20:05:01
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	05 Nov 2020 20:05:01
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	05 Nov 2020 20:05:01

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '2 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:27:24

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[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 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	03 Nov 2020 06:27:24
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[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 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 06:56:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 06:56:45
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 06:56:45
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 06:27:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:27:24

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '2 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:27:24

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:27:24

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:27:24

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[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 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:27:24

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:27:24

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	Judith Kirstein (b) (4) (b) (4)	03 Nov 2020 06:27:24

US3162290

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '0'	System	06 Nov 2020 06:56:45

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:14

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '11 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:32:48

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:14

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '12:45'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:32:48

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:14

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '11 Feb 2021 12:45'	System	12 Feb 2021 00:32:48

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:14

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Safety Call (Safety Call)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:32:48

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:14

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:32:48

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 1 (Day 1)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '5 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered '1'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	12 Feb 2021 05:51:37
User entered empty.	System	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:52:06
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Moderate (Moderate)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:34:03

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 2 (Day 2)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '6 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered '1'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	12 Feb 2021 05:51:37
User entered empty.	System	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered 'Mild (Mild)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:09

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 3 (Day 3)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '7 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered '1'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	12 Feb 2021 05:51:37
User entered empty.	System	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:24

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 4 (Day 4)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '8 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered '1'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	12 Feb 2021 05:51:37
User entered empty.	System	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:37

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 5 (Day 5)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '9 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered '1'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	12 Feb 2021 05:51:37
User entered empty.	System	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:35:50

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 6 (Day 6)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '10 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered '1'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	12 Feb 2021 05:51:37
User entered empty.	System	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 05:51:37
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:36:06

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 7 (Day 7)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '11 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '99'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '98.6' F	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Moderate (Moderate)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Moderate (Moderate)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:37:49

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Day 8 (Day 8)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '12 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '0'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '98'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '97.9' F	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 20:00:33

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'Day 9 (Day 9)'	Judith Kirstein (b) (4)	14 Feb 2021 19:51:14
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '13 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:51:14

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	14 Feb 2021 19:51:14
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '98'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:51:14

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	14 Feb 2021 19:51:14

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '97.6' F	Judith Kirstein (b) (4)	14 Feb 2021 19:51:14
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:51:14

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:51:14

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:51:14

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:51:14

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:51:14

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:51:14

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Feb 2021 19:51:14
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	14 Feb 2021 19:51:14
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:51:14

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Feb 2021 19:51:14
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	14 Feb 2021 19:51:14
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:51:14

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Feb 2021 19:51:14
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Feb 2021 19:51:14
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:51:14

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:51:14

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'Day 10 (Day 10)'	Judith Kirstein (b) (4)	14 Feb 2021 19:52:28
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '14 Feb 2021'	Judith Kirstein (b) (4)	14 Feb 2021 19:52:28
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	14 Feb 2021 19:52:28
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '97'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:52:28

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	14 Feb 2021 19:52:28

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '96.8' F	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:52:28

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Feb 2021 19:52:28
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Feb 2021 19:52:28
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Feb 2021 19:52:28
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Feb 2021 19:52:28
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Feb 2021 19:52:28
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:52:28

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Feb 2021 19:52:28
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Feb 2021 19:52:28
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:52:28

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:52:28

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:52:28

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Feb 2021 19:52:28
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	14 Feb 2021 19:52:28

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Feb 2021 19:52:28
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Feb 2021 19:52:28
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Feb 2021 19:52:28
	(b) (4)	

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Day 11 (Day 11)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '15 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '0'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '98'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '97.9' F	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Moderate (Moderate)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 19:59:04

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Day 12 (Day 12)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '16 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '0'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '97'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '%'	System	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '96.8' F	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Mild (Mild)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'None (None)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:12:54

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '11 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:38:11

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[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 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:38:11

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

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 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 00:36:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 00:36:43
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	17 Feb 2021 00:36:43
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 00:38:11
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:38:11

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '11 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:38:11

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:38:11

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:38:11

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[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 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:38:11

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:38:11

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:38:11

US3162290

Folder: Covid-19 Assessment 11 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:14

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:57
User entered '0'	System	17 Feb 2021 00:36:43

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:32:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User accepted default value 'Day 3 (Day 3)'	Judith Kirstein (b) (4)	06 Nov 2020 06:57:33
	(b) (4)	

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:32:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 06:57:33

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:32:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '4 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 06:57:33

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:32:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User accepted default value 'Day 5 (Day 5)'	Judith Kirstein (b) (4)	06 Nov 2020 06:57:33
	(b) (4)	

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:32:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'NA (COVID-19 Negative) (NA)'	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 06:57:33

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:32:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 06:57:33

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:32:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User accepted default value 'Day 7 (Day 7)'	Judith Kirstein (b) (4)	06 Nov 2020 06:57:33
	(b) (4)	

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:32:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'NA (COVID-19 Negative) (NA)'	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 06:57:33

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:32:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 06:57:33

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:32:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User accepted default value 'Day 9 (Day 9)'	Judith Kirstein (b) (4)	06 Nov 2020 06:57:33
	(b) (4)	

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:32:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'NA (COVID-19 Negative) (NA)'	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 06:57:33

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:32:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 06:57:33

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:32:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User accepted default value 'Day 14 (Day 14)'	Judith Kirstein (b) (4)	06 Nov 2020 06:57:33
	(b) (4)	

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:32:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'NA (COVID-19 Negative) (NA)'	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 06:57:33

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:32:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	06 Nov 2020 06:57:33
	(b) (4)	

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:32:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User accepted default value 'Day 21 (Day 21)'	Judith Kirstein (b) (4)	06 Nov 2020 06:57:33
	(b) (4)	

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:32:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'NA (COVID-19 Negative) (NA)'	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 06:57:33

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:32:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 06:57:33

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:32:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User accepted default value 'Day 28 (Day 28)'	Judith Kirstein (b) (4)	06 Nov 2020 06:57:33
	(b) (4)	

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:32:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'NA (COVID-19 Negative) (NA)'	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 06:57:33

US3162290

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:32:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 06:57:33

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:32:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User accepted default value 'Day 3 (Day 3)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:32:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:32:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '13 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:32:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User accepted default value 'Day 5 (Day 5)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:32:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:32:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:19:35
	(b) (4)	
User entered '15 Feb 2021'	Tiffany Williams (b) (4)	16 Feb 2021 19:14:07
	(b) (4)	

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:32:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User accepted default value 'Day 7 (Day 7)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:32:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 00:37:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 00:37:28
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	17 Feb 2021 00:37:28
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 19:14:07
User entered empty.	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:32:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered empty.	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:32:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User accepted default value 'Day 9 (Day 9)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:32:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 00:37:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 00:37:28
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	17 Feb 2021 00:37:28
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 19:14:07
User entered empty.	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:32:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered empty.	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:32:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User accepted default value 'Day 14 (Day 14)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:32:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 00:37:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 00:37:28
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	17 Feb 2021 00:37:28
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 19:14:07
User entered empty.	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:32:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered empty.	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:32:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User accepted default value 'Day 21 (Day 21)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:32:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 00:37:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 00:37:28
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	17 Feb 2021 00:37:28
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 19:14:07
User entered empty.	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:32:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered empty.	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:32:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User accepted default value 'Day 28 (Day 28)'	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:32:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 00:37:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 00:37:28
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	17 Feb 2021 00:37:28
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 19:14:07
User entered empty.	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:32:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered empty.	Tiffany Williams (b) (4) (b) (4)	16 Feb 2021 19:14:07

US3162290

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 19:35:03

US3162290

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '2 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 19:35:03

US3162290

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[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 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Nov 2020 19:35:03

US3162290

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User entered 'SICKD1'	System	04 Nov 2020 19:35:03

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 19:37:07

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '2 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 19:37:07

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '16:01'	(b) (4), (b) (6)	04 Nov 2020 19:37:07

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User entered '2 Nov 2020 16:01'	System	04 Nov 2020 19:37:07

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '67' in	(b) (4), (b) (6)	04 Nov 2020 19:37:07
DataPoint set to visible.	System	04 Nov 2020 19:35:03

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '160' lb	(b) (4), (b) (6)	04 Nov 2020 19:37:07
DataPoint set to visible.	System	04 Nov 2020 19:35:03

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '98.2' F	(b) (4), (b) (6)	04 Nov 2020 19:37:07

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Nov 2020 19:37:07

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:37:07

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '89'	(b) (4), (b) (6)	04 Nov 2020 19:37:07

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User entered 'bpm'	System	04 Nov 2020 19:37:07

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '12'	(b) (4), (b) (6)	04 Nov 2020 19:37:07

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User entered 'breaths/min'	System	04 Nov 2020 19:37:07

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '148'	(b) (4), (b) (6)	04 Nov 2020 19:37:07

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User entered 'mmHg'	System	04 Nov 2020 19:37:07

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '99'	(b) (4), (b) (6)	04 Nov 2020 19:37:07

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User entered 'mmHg'	System	04 Nov 2020 19:37:07

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41

US3162290

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 19:37:31

US3162290

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '2 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 19:37:31

US3162290

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:32:14

[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 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 19:37:47

US3162290

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:32:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '2 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 19:37:47

US3162290

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:30:29

US3162290

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '11 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:30:29

US3162290

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[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 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:30:29

US3162290

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User entered 'SICKD1'	System	12 Feb 2021 00:30:29

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:31:33

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '11 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:31:33

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '15:01'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:31:33

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User entered '11 Feb 2021 15:01'	System	12 Feb 2021 00:31:33

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '67' in	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:31:33
DataPoint set to visible.	System	12 Feb 2021 00:30:29

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '179.6' lb	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:31:33
DataPoint set to visible.	System	12 Feb 2021 00:30:29

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '98.6' F	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:31:33

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:31:33

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:31:33

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '117'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:31:33

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User entered 'bpm'	System	12 Feb 2021 00:31:33

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '13'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:31:33

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User entered 'breaths/min'	System	12 Feb 2021 00:31:33

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '147'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:31:33

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User entered 'mmHg'	System	12 Feb 2021 00:31:33

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '97'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:31:33

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User entered 'mmHg'	System	12 Feb 2021 00:31:33

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41

US3162290

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:14

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41

US3162290

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:31:48

US3162290

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:47
	(b) (4)	
User entered '11 Feb 2021'	Tiffany Williams (b) (4)	12 Feb 2021 00:31:48
	(b) (4)	

US3162290

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:32:14

[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 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:31:56

US3162290

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:32:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:47
User entered '11 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 00:31:56

US3162290

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

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 18:51:19

US3162290

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

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:19:35
	(b) (4)	
User entered '24 Feb 2021'	Tiffany Williams (b) (4)	25 Feb 2021 18:51:19
	(b) (4)	

US3162290

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

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[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 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 18:51:19

US3162290

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

Form: Visit Date

Generated On: 09 Jun 2021 15:32:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered 'UNBLND_DECIDE'	System	25 Feb 2021 18:51:19

US3162290

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:19:35
	(b) (4)	
User entered '24 Feb 2021'	Tiffany Williams (b) (4)	25 Feb 2021 18:51:55
	(b) (4)	

US3162290

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:14

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:19:35
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:54:48

US3162290

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:14

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 18:51:55

US3162290

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:14

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:19:35
	(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 09:54:48

US3162290

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:14

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:19:35
	(b) (4)	
User entered '24 Feb 2021'	Tiffany Williams (b) (4)	25 Feb 2021 18:51:55
	(b) (4)	

US3162290

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:14

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'mRNA-1273 (mRNA-1273)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 18:51:55

US3162290

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:14

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'mRNA-1273 (mRNA-1273)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 18:51:55

US3162290

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:14

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'mRNA-1273 (mRNA-1273)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 18:51:55

US3162290

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:14

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:19:35
	(b) (4)	
User entered 'No (N)'	Tiffany Williams (b) (4)	25 Feb 2021 18:51:55
	(b) (4)	

US3162290

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:14

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered empty.	System	25 Feb 2021 18:51:55

US3162290

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:14

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered empty.	System	25 Feb 2021 18:51:55

US3162290

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 18:52:20

US3162290

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:19:35
	(b) (4)	
User entered '24 Feb 2021'	Tiffany Williams (b) (4)	25 Feb 2021 18:52:20
	(b) (4)	

US3162290

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:19:35
	(b) (4)	
User entered '13:50'	Tiffany Williams (b) (4)	25 Feb 2021 18:52:20
	(b) (4)	

US3162290

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered '24 Feb 2021 13:50'	System	25 Feb 2021 18:52:20

US3162290

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:32:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 18:52:37

US3162290

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:19:35
	(b) (4)	
User entered '24 Feb 2021'	Tiffany Williams (b) (4)	25 Feb 2021 18:52:37
	(b) (4)	

US3162290

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:32:14

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '13:51'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 18:52:37

US3162290

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:32:14

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:19:36
User entered '24 Feb 2021 13:51'	System	25 Feb 2021 18:52:37

US3162290

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:32:14

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	04 Nov 2020 19:08:57
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:10:07

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User closed query 'Per MM: Please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 21:43:55
Query 'Per MM: Please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'Subject had illness visit on 02Nov20' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	22 Dec 2020 23:12:56
User opened query 'Per MM: Please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 14:50:17
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:31:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:31:43
Data point term sent to Coder	System	08 Nov 2020 00:27:52
User closed query 'For coding purposes, please clarify/provide more information for term VIRAL SYNDROME.' (Site from System).	System	08 Nov 2020 00:27:21
Query 'For coding purposes, please clarify/provide more information for term VIRAL SYNDROME.' answered with 'B34.9 in ICD-10' (Site from System).	Judith Kirstein (b) (4) (b) (4)	08 Nov 2020 00:27:21
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	08 Nov 2020 00:27:13
User entered 'VIRAL INFECTION, UNSPECIFIED' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	08 Nov 2020 00:27:13
User opened query 'For coding purposes, please clarify/provide more information for term VIRAL SYNDROME.' (Site from System).	Coder Import (b) (4) (b) (4)	07 Nov 2020 20:57:53
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 19:32:27

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	04 Nov 2020 19:32:27
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	04 Nov 2020 19:31:45
User entered 'Viral syndrome'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 06:58:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 06:58:16
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 06:58:16
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 19:31:01
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '26 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	06 Nov 2020 06:58:33
User entered empty; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 06:58:33
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	04 Nov 2020 19:31:01
User entered '01:00'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User entered empty.	System	06 Nov 2020 06:58:33
User entered '26 Oct 2020 01:00'	System	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 07:00:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Nov 2020 07:00:17
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	06 Nov 2020 07:00:17
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Nov 2020 07:00:03
User entered '5 Nov 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 07:00:03
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User entered empty.	System	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'None (NONE)'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'I'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	06 Nov 2020 07:00:17
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[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 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User entered '0'	System	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10
User entered 'I'	System	04 Nov 2020 19:31:01

US3162290

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:10

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User closed query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).		01 Apr 2021 09:45:58
Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'Per CRIO, SARS-CoV-2 result is negative. This is not a symptom of covid and was evaluated for COVID-19 via nasal/saliva sample. ' (Site from DM).		31 Mar 2021 21:08:58
User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).		26 Mar 2021 15:45:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 04:15:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 04:15:38
Data point term sent to Coder	System	12 Feb 2021 04:14:25
User entered 'viral infection, unspecified'	Jessica Fisher (b) (4) (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '05 Feb 2021'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User entered empty.	System	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
Signature has been broken.	Jessica Fisher (b) (4)	25 Feb 2021 02:33:12
User entered 'No (N)' reason for change: New Information	Jessica Fisher (b) (4)	25 Feb 2021 02:33:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 04:14:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Feb 2021 04:14:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessica Fisher (b) (4)	12 Feb 2021 04:14:21
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 04:14:06
User entered empty.	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Mar 2021 04:43:45
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	02 Mar 2021 04:43:45
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Feb 2021 02:33:12
Signature has been broken.	Jessica Fisher (b) (4)	25 Feb 2021 02:33:12
User entered '16 Feb 2021' reason for change: New Information	Jessica Fisher (b) (4)	25 Feb 2021 02:33:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User entered empty.	System	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'I'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
Signature has been broken.	Jessica Fisher (b) (4)	02 Mar 2021 04:43:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Jessica Fisher (b) (4)	02 Mar 2021 04:43:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[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 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	Jessica Fisher (b) (4)	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User entered '0'	System	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14
User entered 'I'	System	12 Feb 2021 04:14:06

US3162290

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:14

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:52:51
User entered		12 Mar 2021 15:52:36
'USA-US074-2021-mRNA-1273-P301000018'		
User entered 'New'		12 Mar 2021 15:52:36

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	19 Mar 2021 21:02:18
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Male reproductive tract infections, PT: Orchitis, LLT: Acute epididymo-orchitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 06:15:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 06:15:39
Data point term sent to Coder	System	16 Mar 2021 17:22:15
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 17:21:58
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 17:21:58
User entered 'ACUTE LEFT EPIDIDYMo-orchitis' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 17:21:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Male reproductive tract infections, PT: Epididymitis, LLT: Epididymitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 22:09:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 22:09:49
Data point term sent to Coder	System	12 Mar 2021 01:42:33
User entered 'acute left epididymitis'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered '6 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). DataPoint Un-verified.	System Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:38:51 15 Apr 2021 21:38:51
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:38:51
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:38:51
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). DataPoint Verified.	System (b) (4), (b) (6)	15 Apr 2021 21:38:27 15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'End date provided' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 16:23:49
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:39:04
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:38:27
User entered '9 Apr 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:38:27
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		19 Mar 2021 23:05:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered 'Grade 4 (Grade 4)'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered '10 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered '11 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:10:36
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	12 Mar 2021 01:41:53
	(b) (4)	

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 00:44:29
User closed query 'Please tick the box for Concomitant Procedures, because the subject was hospitalized and had a CT w/o contrast, US, and an EKG. Thank you.' (Site from CRA).		16 Apr 2021 00:43:47
Query 'Please tick the box for Concomitant Procedures, because the subject was hospitalized and had a CT w/o contrast, US, and an EKG. Thank you.' answered with 'Ticked' (Site from CRA).	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:39:15
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:38:27
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:38:27
User entered '1' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:38:27
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User opened query 'Please tick the box for Concomitant Procedures, because the subject was hospitalized and had a CT w/o contrast, US, and an EKG. Thank you.' (Site from CRA).		15 Apr 2021 18:49:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 16:26:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 00:44:32
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Updated' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:39:24
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:38:27
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:38:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:38:27
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		19 Mar 2021 23:05:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 04:10:36
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:38:27
User entered 'SUBJECT HAD ONSET OF LEFT TESTICULAR AND LOW ABDOMINAL PAIN ON 06MAR21 THAT LED TO ER VISIT ON 10MAR21, AND ADMISSION TO HOSPITAL OVERNIGHT FROM 10MAR TO 11MAR21. COVID TEST IN ER WAS NEGATIVE. TREATED WITH LEVOFLOXACIN IV AND THEN PO. TESTICULAR ULTRASOUND SHOWED LEFT EPIDIDYMO-ORCHITIS AND SMALL COMPLEX LEFT HYDROCELE WITH SEPTATIONS. NON-CONTRAST CT OF ABDOMEN AND PELVIS SHOWED MILD WALL THICKENING OF THE MID THROUGH DISTAL RECTUM WITH PROMINENT SURROUNDING LYMPH NODES AND THE LEFT HYDROCELE. ECG SHOWED SINUS TACHYCARDIA. SUBJECT HAD WBC COUNT OF 19,200 K/UL ON 10MAR21, DOWN TO 13,500 ON 11MAR21. RAPID CHLAMYDIA AND GONORRHEA TESTS WERE NEGATIVE. IN ER, ON 10MAR, HEART RATE WAS 127 AND REACHED MAX OF 135, DOWN TO 101 BY 11MAR21. DISCHARGED ON LEVOFLOXACIN 500 MG DAILY UNTIL 20MAR, IBUPROFEN 600 MG BID, ACETAMINOPHEN 500 MG BID. Per phone call with subject on 15APR21, pain resolved on 09APR21 and pain meds were last taken on 07APR2021.' reason for change: Data Entry Error DataPoint Verified.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:38:27
	(b) (4), (b) (6)	15 Apr 2021 18:53:02
User closed query 'PV Query: Please confirm date and type of COVID test performed in ER. If unknown, please indicate so.' (Site from Safety).		05 Apr 2021 15:24:03

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:23:57
User entered 'SUBJECT HAD ONSET OF LEFT TESTICULAR AND LOW ABDOMINAL PAIN ON 06MAR21 THAT LED TO ER VISIT ON 10MAR21, AND ADMISSION TO HOSPITAL OVERNIGHT FROM 10MAR TO 11MAR21. COVID TEST IN ER WAS NEGATIVE. TREATED WITH LEVOFLOXACIN IV AND THEN PO. TESTICULAR ULTRASOUND SHOWED LEFT EPIDIDYMO-ORCHITIS AND SMALL COMPLEX LEFT HYDROCELE WITH SEPTATIONS. NON-CONTRAST CT OF ABDOMEN AND PELVIS SHOWED MILD WALL THICKENING OF THE MID THROUGH DISTAL RECTUM WITH PROMINENT SURROUNDING LYMPH NODES AND THE LEFT HYDROCELE. ECG SHOWED SINUS TACHYCARDIA. SUBJECT HAD WBC COUNT OF 19,200 K/uL ON 10MAR21, DOWN TO 13,500 ON 11MAR21. Rapid chlamydia and gonorrhea tests were negative. IN ER, ON 10MAR, HEART RATE WAS 127 AND REACHED MAX OF 135, DOWN TO 101 BY 11MAR21. DISCHARGED ON LEVOFLOXACIN 500 MG DAILY UNTIL 20MAR, IBUPROFEN 600 MG BID, ACETAMINOPHEN 500 MG BID.' reason for change: Data Entry Error	Judith Kirstein (b) (4)	04 Apr 2021 16:42:51
Query 'PV Query: Please confirm date and type of COVID test performed in ER. If unknown, please indicate so.' answered with 'On 10MAR2021, subject had Biofire NP swab' (Site from Safety).	Judith Kirstein (b) (4)	04 Apr 2021 16:41:24

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'The relevant test results are in narrative. ' (Site from Safety). Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	04 Apr 2021 16:33:10
	Judith Kirstein (b) (4) (b) (4)	21 Mar 2021 23:46:21
User entered 'SUBJECT HAD ONSET OF LEFT TESTICULAR AND LOW ABDOMINAL PAIN ON 06MAR21 THAT LED TO ER VISIT ON 10MAR21, AND ADMISSION TO HOSPITAL OVERNIGHT FROM 10MAR TO 11MAR21. COVID TEST IN ER WAS NEGATIVE. TREATED WITH LEVOFLOXACIN IV and then PO. Testicular ultrasound showed left epididymo-orchitis and small complex left hydrocele with septations. Non-contrast CT of abdomen and pelvis showed mild wall thickening of the mid through distal rectum with prominent surrounding lymph nodes and the left hydrocele. ECG showed sinus tachycardia. Subject had WBC count of 19,200 on 10MAR21, down to 13,500 on 11Mar21. In ER, on 10Mar, heart rate was 127 and reached max of 135, down to 101 by 11Mar21. Discharged on Levofloxacin 500 mg daily until 20Mar, Ibuprofen 600 mg BID, Acetaminophen 500 mg BID.' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Mar 2021 23:46:21
User opened query 'PV Query: Please confirm date and type of COVID test performed in ER. If unknown, please indicate so.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 23:05:19

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) (b) (4) Judith Kirstein (b) (4) (b) (4)	19 Mar 2021 23:05:12 19 Mar 2021 21:02:18
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 17:21:58
User entered 'SUBJECT HAD ONSET OF LEFT TESTICULAR AND LOW ABDOMINAL PAIN ON 06MAR21 THAT LED TO ER VISIT ON 10MAR21, AND ADMISSION TO HOSPITAL OVERNIGHT FROM 10MAR TO 11MAR21. COVID TEST IN ER WAS NEGATIVE. TREATED WITH LEVOFLOXACIN.' reason for change: Data Entry Error User signature succeeded.	Judith Kirstein (b) (4) (b) (4) Judith Kirstein (b) (4) (b) (4)	16 Mar 2021 17:21:58 16 Mar 2021 04:10:36
User entered 'Subject had onset of left testicular and low abdominal pain on 06MAR21 that led to ER visit on 10MAR21, and admission to hospital overnight from 10MAR to 11MAR21. Covid test in ER was negative according to subject. Treated with Levofloxacin.'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 01:41:53

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Reproductive tract and breast disorders congenital, HLT: Male reproductive tract disorders congenital, PT: Hydrocele, LLT: Hydrocele - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:12:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:12:38
Data point term sent to Coder	System	22 Mar 2021 16:43:38
User entered 'Small complex left hydrocele'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered '10 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

None

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Mar 2021 16:43:11
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 16:43:11
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Mar 2021 16:42:57
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:48
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Mar 2021 16:42:57

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus tachycardia, LLT: Sinus tachycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 16:48:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 16:48:52
Data point term sent to Coder	System	22 Mar 2021 16:48:01
User entered 'Sinus tachycardia'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered '10 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User closed query 'Start time is present for an AE that System did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		22 Mar 2021 16:47:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 16:47:52
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Mar 2021 16:47:34
User entered '11:41'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User entered empty.	System	22 Mar 2021 16:47:52
User entered '10 Mar 2021 11:41'	System	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered '11 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	22 Mar 2021 16:47:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 16:47:52
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	22 Mar 2021 16:47:34
User entered '09:12'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User entered empty.	System	22 Mar 2021 16:47:52
User entered '11 Mar 2021 09:12'	System	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered 'l'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[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 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:51
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User entered '0'	System	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19
User entered 'I'	System	22 Mar 2021 16:47:34

US3162290

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:15:19

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User closed query 'Subject presented with a Fever upon admission to the hospital. Please verify if this should be added as an AE. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 00:53:43
Query 'Subject presented with a Fever upon admission to the hospital. Please verify if this should be added as an AE. Thank you.' answered with 'No, it was part of the testicular infection presentation' (Site from CRA).	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:40:14
User opened query 'Subject presented with a Fever upon admission to the hospital. Please verify if this should be added as an AE. Thank you.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 18:53:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Rectal inflammations NEC, PT: Proctitis, LLT: Rectal inflammatory process - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 14:41:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 14:41:36
Data point term sent to Coder	System	22 Mar 2021 16:51:03
User entered 'Inflammatory Changes of Rectal Wall'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered '10 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered 'I'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:55
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Mar 2021 16:50:28

US3162290

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Mar 2021 16:50:28

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Yes (Y)' reason for change: New Information	Jessica Fisher (b) (4)	27 Oct 2020 03:57:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:11:42

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 04:00:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 04:00:36
Data point term sent to Coder	System	27 Oct 2020 03:59:12
User entered 'Claritin'	Jessica Fisher (b) (4) (b) (4)	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'No (N)'	Jessica Fisher (b) (4)	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'seasonal allergies'	Jessica Fisher (b) (4) (b) (4)	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '10'	Jessica Fisher (b) (4) (b) (4)	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'mg (mg)'	Jessica Fisher (b) (4)	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	Jessica Fisher (b) (4) (b) (4)	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'as needed (PRN)'	Jessica Fisher (b) (4) (b) (4)	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	Jessica Fisher (b) (4)	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Oral (ORAL)'	Jessica Fisher (b) (4) (b) (4)	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	Jessica Fisher (b) (4)	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'un UNK 2015'	Jessica Fisher (b) (4) (b) (4)	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	Jessica Fisher (b) (4)	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	Jessica Fisher (b) (4)	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'No (N)'	Jessica Fisher (b) (4)	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 03:58:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: MUCINEX DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 21:37:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 21:37:53
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 00:03:11
Data point term sent to Coder	System	10 Nov 2020 00:00:06
Coding entries removed.	Judith Kirstein (b) (4)	09 Nov 2020 23:59:50
	(b) (4)	
Coding entries removed.	Judith Kirstein (b) (4)	09 Nov 2020 23:59:50
	(b) (4)	
User entered 'MUCINEX DM (DEXTROMETHORPHAN/GUAIFENESIN)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	09 Nov 2020 23:59:50
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: MUCINEX DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 19:07:27
	(b) (4)	

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	04 Nov 2020 19:07:27
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	04 Nov 2020 19:07:07
User entered 'Mucinex DM'	(b) (4), (b) (6)	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'VIRAL INFECTION, UNSPECIFIED' reason for change: Data Entry Error	Judith Kirstein (b) (4)	10 Nov 2020 00:03:01
	(b) (4)	
User entered 'ACUTE VIRAL INFECTION, UNSPECIFIED' reason for change: Data Entry Error	Judith Kirstein (b) (4)	09 Nov 2020 23:59:50
	(b) (4)	
User entered 'viral syndrome'	(b) (4), (b) (6)	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered '20/400' reason for change: Data Entry Error	Judith Kirstein (b) (4)	09 Nov 2020 23:59:50
	(b) (4)	
User entered '15'	(b) (4), (b) (6)	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	09 Nov 2020 23:59:50
	(b) (4)	
User entered 'mL (mL)'	(b) (4), (b) (6)	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'twice daily (BID)'	(b) (4), (b) (6)	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered '27 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered '28 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User entered '2'	System	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User entered '1'	System	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:25
User entered '804 (804)'	System	04 Nov 2020 19:06:19

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 00:04:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 00:04:38
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 00:04:11
Coding entries removed.	Judith Kirstein (b) (4)	10 Nov 2020 00:03:24
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 19:08:27
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 19:08:27
	(b) (4)	
Data point term sent to Coder	System	04 Nov 2020 19:08:12
User entered 'Tylenol'	(b) (4), (b) (6)	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'VIRAL INFECTION, UNSPECIFIED' reason for change: Data Entry Error	Judith Kirstein (b) (4)	10 Nov 2020 00:03:24
	(b) (4)	
User entered 'viral syndrome'	(b) (4), (b) (6)	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered '500'	(b) (4), (b) (6)	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'as needed (PRN)'	(b) (4), (b) (6)	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered '27 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered '28 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User entered empty.	System	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User entered empty.	System	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:36
User entered empty.	System	04 Nov 2020 19:07:58

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:08:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, PRODUCT: ARGININE, PRODUCTS YNonym: L-ARGININE [ARGININE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:44:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:44:01
Data point term sent to Coder	System	17 Nov 2020 22:11:25
User entered 'L-Arginine'	(b) (4), (b) (6)	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:08:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:08:44
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 HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).		17 Feb 2021 04:04:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
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 HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'No worsening. He wanted to try a natural method to control it.' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	03 Feb 2021 05:43:48
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 HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:09:20
User entered 'Hypertension'	(b) (4), (b) (6)	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:08:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '1000'	(b) (4), (b) (6)	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:08:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:08:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:08:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:08:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:08:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:08:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:08:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '12 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:08:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:08:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:08:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:08:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 22:11:20

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 04:16:42
	(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 Feb 2021 04:16:42
	(b) (4)	
Data point term sent to Coder	System	12 Feb 2021 04:15:26
User entered 'Tylenol'	Jessica Fisher (b) (4)	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'viral infection, unspecified'	Jessica Fisher (b) (4)	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered '500'	Jessica Fisher (b) (4)	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'mg (mg)'	Jessica Fisher (b) (4)	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered empty.	Jessica Fisher (b) (4)	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'as needed (PRN)'	Jessica Fisher (b) (4)	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered empty.	Jessica Fisher (b) (4)	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'Oral (ORAL)'	Jessica Fisher (b) (4)	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered empty.	Jessica Fisher (b) (4)	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
Signature has been broken.	Jessica Fisher (b) (4)	16 Feb 2021 00:59:43
User entered '07 Feb 2021' reason for change: New Information	Jessica Fisher (b) (4)	16 Feb 2021 00:59:43
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered '05 Feb 2021'	Jessica Fisher (b) (4)	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered '0'	Jessica Fisher (b) (4)	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
Signature has been broken.	Jessica Fisher (b) (4)	16 Feb 2021 00:59:43
User entered 'No (N)' reason for change: New Information	Jessica Fisher (b) (4)	16 Feb 2021 00:59:43
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
Signature has been broken.	Jessica Fisher (b) (4)	16 Feb 2021 00:59:43
User entered '09 Feb 2021' reason for change: New Information	Jessica Fisher (b) (4)	16 Feb 2021 00:59:43
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered empty.	Jessica Fisher (b) (4)	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:53:41
	(b) (4)	
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User entered empty.	System	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User entered empty.	System	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:17
User entered empty.	System	12 Feb 2021 04:15:10

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:25:59
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 12:17:26
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 12:17:26
	(b) (4)	
Data point term sent to Coder	System	22 Mar 2021 16:54:09
Coding entries removed.	(b) (4), (b) (6)	22 Mar 2021 16:53:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Mar 2021 08:35:04
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Mar 2021 08:35:04
	(b) (4)	
Data point term sent to Coder	System	12 Mar 2021 04:08:55
User entered 'levofloxacin'	Jessica Fisher (b) (4)	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:25:59
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:25:59
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'ACUTE LEFT EPIDIDYMO-ORCHITIS' reason for change: New Information	(b) (4), (b) (6)	22 Mar 2021 16:53:35
User entered 'acute left epididymitis'	Jessica Fisher (b) (4)	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:25:59
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '500'	Jessica Fisher (b) (4)	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:25:59
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'mg (mg)'	Jessica Fisher (b) (4)	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:25:59
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:25:59
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'once daily (QD)'	Jessica Fisher (b) (4)	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:25:59
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:25:59
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'Oral (ORAL)'	Jessica Fisher (b) (4)	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:25:59
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:25:59
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '12 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	22 Mar 2021 16:53:35
User entered '10 Mar 2021'	Jessica Fisher (b) (4)	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:25:59
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:25:59
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	22 Mar 2021 16:53:35
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:25:59
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '20 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	22 Mar 2021 16:53:35
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:25:59
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
User entered '1'	System	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
User entered '1'	System	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:41
User entered '804 (804)'	System	12 Mar 2021 04:08:41

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:28:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 12:17:26
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 12:17:26
	(b) (4)	
Data point term sent to Coder	System	22 Mar 2021 16:56:11
User entered 'LEVOFLOXACIN'	(b) (4), (b) (6)	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:28:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:28:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'ACUTE LEFT EPIDIDYMO-ORCHITIS'	(b) (4), (b) (6)	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:28:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '500'	(b) (4), (b) (6)	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
User closed query 'Per Hospital Records page 7, please verify if the dose unit should be listed as 500m/100mL/Hr' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 00:57:17
Query 'Per Hospital Records page 7, please verify if the dose unit should be listed as 500m/100mL/Hr' answered with 'No it is correct as written' (Site from CRA).	Judith Kirstein (b) (4)	15 Apr 2021 21:57:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:28:39
User opened query 'Per Hospital Records page 7, please verify if the dose unit should be listed as 500m/100mL/Hr' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:28:21
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:28:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:28:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:28:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:28:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:28:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:28:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '10 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:28:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:28:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:28:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '11 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:28:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
User entered '1'	System	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
User entered '1'	System	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:12
User entered '804 (804)'	System	22 Mar 2021 16:55:40

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:14:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
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)	22 Mar 2021 16:59:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Mar 2021 16:59:49
	(b) (4)	
Data point term sent to Coder	System	22 Mar 2021 16:59:13
User entered 'ACETAMINOPHEN' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 16:58:12
Data point term sent to Coder	System	22 Mar 2021 16:58:11
User entered 'ACETANUBOPHEN'	(b) (4), (b) (6)	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:14:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:14:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'ACUTE LEFT EPIDIDYMO-ORCHITIS'	(b) (4), (b) (6)	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:14:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '1000'	(b) (4), (b) (6)	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:14:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:14:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:14:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'once (ONCE)'	(b) (4), (b) (6)	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:14:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:14:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:14:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:14:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '11 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:14:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:14:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:14:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '11 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:14:39
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User entered empty.	System	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User entered empty.	System	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User entered empty.	System	22 Mar 2021 16:57:35

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:32
Query 'Per Hospital Medical Record page 7, it appears the Ibuprofen order was cancelled, please verify. Thank you.' canceled (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:34:20
User opened query 'Per Hospital Medical Record page 7, it appears the Ibuprofen order was cancelled, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:21:22
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Mar 2021 15:07:13
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Mar 2021 15:07:13
	(b) (4)	
Data point term sent to Coder	System	22 Mar 2021 17:00:14
User entered 'IBUPROFEN'	(b) (4), (b) (6)	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:32
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:32
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'ACUTE LEFT EPIDIDYMO-ORCHITIS'	(b) (4), (b) (6)	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:32
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '400'	(b) (4), (b) (6)	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:32
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:32
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:32
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'once (ONCE)'	(b) (4), (b) (6)	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:32
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:32
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:32
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:32
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '11 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:32
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:32
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:32
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '11 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:32
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
User entered empty.	System	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
User entered empty.	System	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:41
User entered empty.	System	22 Mar 2021 16:59:27

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:58:43
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 09:19:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 09:19:52
	(b) (4)	
Data point term sent to Coder	System	22 Mar 2021 17:01:15
User entered 'MORPHINE SULFATE'	(b) (4), (b) (6)	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:58:43
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:58:43
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'ACUTE LEFT EPIDIDYMO-ORCHITIS'	(b) (4), (b) (6)	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:58:43
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '4'	(b) (4), (b) (6)	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:58:43
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:58:43
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:58:43
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'once (ONCE)'	(b) (4), (b) (6)	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:58:43
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:58:43
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:58:43
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:58:43
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '10 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:58:43
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:58:43
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:58:43
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '10 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:58:43
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User entered empty.	System	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User entered empty.	System	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User entered empty.	System	22 Mar 2021 17:00:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User closed query 'Per Hospital Record page 8, Zofran (Odansetron PF) 4 mg, was given from 10-11 Mar 2021, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 22:29:55
Query 'Per Hospital Record page 8, Zofran (Odansetron PF) 4 mg, was given from 10-11 Mar 2021, please verify. Thank you.' answered with 'I cannot find that. Can you send me a screen shot?' (Site from CRA).	Judith Kirstein (b) (4)	15 Apr 2021 22:07:16
User opened query 'Per Hospital Record page 8, Zofran (Odansetron PF) 4 mg, was given from 10-11 Mar 2021, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:38:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:03
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Mar 2021 05:35:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Mar 2021 05:35:25
Data point term sent to Coder	System	22 Mar 2021 17:02:16
User entered 'OXYCODONE/ACETAMINOPHEN'	(b) (4), (b) (6)	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:03
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 17:02:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Mar 2021 17:02:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 17:02:22
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 17:02:15
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:03
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'ACUTE LEFT EPIDIDYMO-ORCHITIS'	(b) (4), (b) (6)	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:03
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '5/325'	(b) (4), (b) (6)	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:03
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:03
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:03
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'once (ONCE)'	(b) (4), (b) (6)	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:03
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:03
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:03
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:03
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '10 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:03
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:03
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:03
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '10 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:03
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User entered empty.	System	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User entered empty.	System	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User entered empty.	System	22 Mar 2021 17:02:15

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:27
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SALINE [SODIUM CHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Mar 2021 08:30:29
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Mar 2021 08:30:29
	(b) (4)	
Data point term sent to Coder	System	22 Mar 2021 17:04:17
User entered '0.9% SALINE'	(b) (4), (b) (6)	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:27
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:27
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'SINUS TACHYCARDIA'	(b) (4), (b) (6)	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:19:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:23
DataPoint Un-verified.	Judith Kirstein (b) (4)	15 Apr 2021 22:12:20
	(b) (4)	
Signature has been broken.	Judith Kirstein (b) (4)	15 Apr 2021 22:12:20
	(b) (4)	
User entered '100' reason for change: Data Entry Error	Judith Kirstein (b) (4)	15 Apr 2021 22:12:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:27
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '1000'	(b) (4), (b) (6)	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:27
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'mL (mL)'	(b) (4), (b) (6)	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:27
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:19:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:25
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	15 Apr 2021 22:12:20
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	15 Apr 2021 22:12:20
DataPoint Un-verified.	Judith Kirstein (b) (4)	15 Apr 2021 22:12:20
	(b) (4)	
Signature has been broken.	Judith Kirstein (b) (4)	15 Apr 2021 22:12:20
	(b) (4)	
User entered 'other (OTHER)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	15 Apr 2021 22:12:20
	(b) (4)	
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	15 Apr 2021 22:11:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:27
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'once (ONCE)'	(b) (4), (b) (6)	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:19:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:27
DataPoint Un-verified.	Judith Kirstein (b) (4)	15 Apr 2021 22:12:20
	(b) (4)	
Signature has been broken.	Judith Kirstein (b) (4)	15 Apr 2021 22:12:20
	(b) (4)	
User entered 'per hour' reason for change: Data Entry Error	Judith Kirstein (b) (4)	15 Apr 2021 22:12:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:27
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:27
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:27
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:27
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '10 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:27
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:27
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
	(b) (4)	
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:19:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:30
User closed query 'Per Hospital Records page 8, it appears the stop date for the saline should be 11 Mar 2021, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 01:00:01
Query 'Per Hospital Records page 8, it appears the stop date for the saline should be 11 Mar 2021, please verify. Thank you.' answered with 'updated' (Site from CRA).	Judith Kirstein (b) (4)	15 Apr 2021 22:12:47
	(b) (4)	
DataPoint Un-verified.	Judith Kirstein (b) (4)	15 Apr 2021 22:11:18
	(b) (4)	
Signature has been broken.	Judith Kirstein (b) (4)	15 Apr 2021 22:11:18
	(b) (4)	
User entered '11 Mar 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4)	15 Apr 2021 22:11:18
	(b) (4)	
User opened query 'Per Hospital Records page 8, it appears the stop date for the saline should be 11 Mar 2021, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:32:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:27
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered '10 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 17:03:34
	(b) (4)	

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:27
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
User entered empty.	System	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
User entered empty.	System	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:31
User entered empty.	System	22 Mar 2021 17:03:34

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:10:45
Query 'Please update your con med log in your eSource' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 01:10:12
User opened query 'Please update your con med log in your eSource' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 01:03:56
User closed query 'Unable to find this medication and dose in the record. Please verify and point out the page #. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 01:03:56
Query 'Unable to find this medication and dose in the record. Please verify and point out the page #. Thank you.' answered with 'Started after he went home' (Site from CRA).	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 22:14:36
User opened query 'Unable to find this medication and dose in the record. Please verify and point out the page #. Thank you.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:36:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 15:07:13
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 Mar 2021 15:07:13
Data point term sent to Coder	System	22 Mar 2021 17:06:20
User entered 'IBUPROFEN'	(b) (4), (b) (6)	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:10:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:10:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered 'ACUTE LEFT EPIDIDYMO-ORCHITIS'	(b) (4), (b) (6)	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:10:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered '600'	(b) (4), (b) (6)	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:10:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:10:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:10:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered 'twice daily (BID)'	(b) (4), (b) (6)	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:10:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:10:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:10:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:10:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered '11 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:10:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:10:45
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 22:15:04
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 22:15:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:10:45
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 22:15:04
User entered '7 Apr 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 22:15:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:10:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Mar 2021 17:05:21

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:07:16
User closed query 'Per Hospital Records, page 43, Arginine Oxoglurate (L-Arginine, Alpha-Ketoglutarat, Oral) was provided to the subject (with out dose information listed). Please verify if this should be entered into eSource and EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 01:05:12
Query 'Per Hospital Records, page 43, Arginine Oxoglurate (L-Arginine, Alpha-Ketoglutarat, Oral) was provided to the subject (with out dose information listed). Please verify if this should be entered into eSource and EDC. Thank you.' answered with 'See con med #4 in EDC' (Site from CRA).	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 22:17:22
User opened query 'Per Hospital Records, page 43, Arginine Oxoglurate (L-Arginine, Alpha-Ketoglutarat, Oral) was provided to the subject (with out dose information listed). Please verify if this should be entered into eSource and EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:08:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
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)	22 Mar 2021 17:07:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 17:07:51
Data point term sent to Coder	System	22 Mar 2021 17:07:24
User entered 'ACETAMINOPHEN'	(b) (4), (b) (6)	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:07:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:07:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered 'ACUTE LEFT EPIDIDYMO-ORCHITIS'	(b) (4), (b) (6)	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:07:16
User closed query 'Unable to find Acetaminophen dose in medical records for this date, please verify (also provide page #. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 01:06:14
Query 'Unable to find Acetaminophen dose in medical records for this date, please verify (also provide page #. Thank you.' answered with 'Started after he went home' (Site from CRA).	Judith Kirstein (b) (4)	15 Apr 2021 22:15:42
User opened query 'Unable to find Acetaminophen dose in medical records for this date, please verify (also provide page #. Thank you.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:40:18
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:28:46
User entered '500'	(b) (4), (b) (6)	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:07:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:07:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:07:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered 'twice daily (BID)'	(b) (4), (b) (6)	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:07:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:07:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:07:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:07:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered '11 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:07:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:07:16
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 22:16:06
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 22:16:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:07:16
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 22:16:06
User entered '7 Apr 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 22:16:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:07:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:28:46
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Mar 2021 17:06:45

US3162290

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:32:14

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:10
User closed query 'Please update this to "yes", because the subject was hospitalized and had a CT w/o contrast, US, and an EKG. Please update the Concomitant Procedure Log with this information. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 22:44:49
Query 'Please update this to "yes", because the subject was hospitalized and had a CT w/o contrast, US, and an EKG. Please update the Concomitant Procedure Log with this information. Thank you.' answered with 'updated' (Site from CRA).	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:55:25
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:41:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:41:06
User opened query 'Please update this to "yes", because the subject was hospitalized and had a CT w/o contrast, US, and an EKG. Please update the Concomitant Procedure Log with this information. Thank you.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 18:48:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:53:41
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 17:10:19

US3162290

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:32:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:22
User entered '10 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:43:32

US3162290

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:32:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:22
User entered 'CT of abdomen and pelvis without contrast'	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:43:32

US3162290

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:22
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:43:32

US3162290

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:32:14

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:22
User entered empty.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:43:32

US3162290

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:32:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:22
User entered '10 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:50:05

US3162290

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:32:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:22
User entered 'Testicular ultrasound'	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:50:05

US3162290

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:22
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:50:05

US3162290

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:32:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:22
User entered empty.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:50:05

US3162290

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:32:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:22
User entered '10 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:54:24

US3162290

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:32:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:22
User entered 'ecg'	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:54:24

US3162290

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:32:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:22
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:54:24

US3162290

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:32:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:22
User entered empty.	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 21:54:24

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'USA-US074-2021-MRNA-1273-P301000018'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Yes (Y)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Yes (Y)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Judith'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Kirstein'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'BANNING'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'CA'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered '92220'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 14:52:57
User entered 'US'	System	12 Mar 2021 15:53:12

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	16 Apr 2021 16:28:09
User entered '4'	System	05 Apr 2021 15:25:04
User entered '3'	System	22 Mar 2021 14:27:22
User entered '2'	System	17 Mar 2021 14:53:05
User entered '1'	System	12 Mar 2021 15:53:12

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'USA-US074-2021-MRNA-1273-P301000018'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Yes (Y)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Yes (Y)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Judith'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Kirstein'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'BANNING'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'CA'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered '92220'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 14:52:57
User entered 'US'	System	12 Mar 2021 15:53:12

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	16 Apr 2021 16:28:09
User entered '4'	System	05 Apr 2021 15:25:04
User entered '3'	System	22 Mar 2021 14:27:22
User entered '2'	System	17 Mar 2021 14:53:05
User entered '1'	System	12 Mar 2021 15:53:12

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:32:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '12/Mar/2021 09:53'	System	12 Mar 2021 15:53:12

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:32:14

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)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 14:52:57
User entered 'I'	(b) (4), (b) (6)	12 Mar 2021 15:53:12

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'USA-US074-2021-MRNA-1273-P301000018'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Yes (Y)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Yes (Y)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Judith'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Kirstein'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'BANNING'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'CA'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered '92220'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 14:52:57
User entered 'US'	System	12 Mar 2021 15:53:12

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	16 Apr 2021 16:28:09
User entered '4'	System	05 Apr 2021 15:25:04
User entered '3'	System	22 Mar 2021 14:27:22
User entered '2'	System	17 Mar 2021 14:53:05
User entered '1'	System	12 Mar 2021 15:53:12

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:32:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '17/Mar/2021 10:53'	System	17 Mar 2021 14:53:05

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:32:14

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)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 14:26:54
User entered 'I'	(b) (4), (b) (6)	17 Mar 2021 14:53:05

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'USA-US074-2021-MRNA-1273-P301000018'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Yes (Y)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Yes (Y)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Judith'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Kirstein'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'BANNING'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'CA'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered '92220'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 14:52:57
User entered 'US'	System	12 Mar 2021 15:53:12

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	16 Apr 2021 16:28:09
User entered '4'	System	05 Apr 2021 15:25:04
User entered '3'	System	22 Mar 2021 14:27:22
User entered '2'	System	17 Mar 2021 14:53:05
User entered '1'	System	12 Mar 2021 15:53:12

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:32:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '22/Mar/2021 09:27'	System	22 Mar 2021 14:27:22

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:32:14

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)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:24:47
User entered 'I'		22 Mar 2021 14:27:22

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'USA-US074-2021-MRNA-1273-P301000018'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Yes (Y)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Yes (Y)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Judith'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Kirstein'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'BANNING'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'CA'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered '92220'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 14:52:57
User entered 'US'	System	12 Mar 2021 15:53:12

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	16 Apr 2021 16:28:09
User entered '4'	System	05 Apr 2021 15:25:04
User entered '3'	System	22 Mar 2021 14:27:22
User entered '2'	System	17 Mar 2021 14:53:05
User entered '1'	System	12 Mar 2021 15:53:12

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:32:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:19:35
	(b) (4)	
User entered '05/Apr/2021 11:25'	System	05 Apr 2021 15:25:04

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:32:14

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)	24 Apr 2021 23:19:35
User entered 'I'	(b) (4), (b) (6)	05 Apr 2021 15:25:04

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'USA-US074-2021-MRNA-1273-P301000018'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Yes (Y)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Yes (Y)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'No (N)'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Judith'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'Kirstein'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'BANNING'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered 'CA'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:53:03
User entered '92220'	System	12 Mar 2021 15:52:36

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 14:52:57
User entered 'US'	System	12 Mar 2021 15:53:12

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	16 Apr 2021 16:28:09
User entered '4'	System	05 Apr 2021 15:25:04
User entered '3'	System	22 Mar 2021 14:27:22
User entered '2'	System	17 Mar 2021 14:53:05
User entered '1'	System	12 Mar 2021 15:53:12

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:32:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:19:35
User entered '16/Apr/2021 09:28'	System	16 Apr 2021 16:28:09

US3162290

Folder: SAE USA-US074-2021-MRNA-1273-P301000018

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:32:14

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)	24 Apr 2021 23:19:35
User entered 'I'	(b) (4), (b) (6)	16 Apr 2021 16:28:09