

US3492237 (Prod: UIC Project WISH CRS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:43:58

All time stamps listed in this document are displayed in GMT

US3492237

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

[Participant ID](#)

US3492237

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

US3492237

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 04:16:50

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Date of Birth (MMM yyyy)	(b) (6) 1960
Age	60
Age Units	YEARS
Age (Derived)	60
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 04:16:50

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Date of Informed Consent (<i>dd MMM yyyy</i>)	22 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 04:16:50

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 04:16:50

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 04:16:50

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Condition	ASTHMA-MILD
Start date (dd MMM yyyy)	UN UNK 1966
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 1966
Start Year (derived)	1966
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 04:16:50

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Condition	GASTRO-ESOPHAGEAL REFLUX DISEASE
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)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 04:16:50

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:16:50

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	22 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:50 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 15:50
Height (<i>xxx.x</i>)	170 cm
Weight (<i>xxx.x</i>)	103 kg
BMI (<i>xxx.x</i>)	35.64014 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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:16:50

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 04:16:50

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

AIRLINE EMPLOYEE

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 04:16:50

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 04:16:50

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What was the date of randomization? (dd MMM yyyy) 22 SEP 2020

What was the participant's randomization number? 115295

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 04:16:50

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

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)	22 SEP 2020
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 15:50
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	16:52 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 16:52
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:16:50

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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) 22 SEP 2020

What was the treatment time? (00:00-23:59) 16:42 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 16:42

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

15:58 (24 HR)

Collection date and time (derived)

22 SEP 2020 15:58

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:05	22 SEP 2020 16:05
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐
No ☒

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

PC Time Stamp

22 SEP 2020 17:03

PC Open Date & Time

22 SEP 2020 17:02

PC Close Date & Time

22 SEP 2020 19:32

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

22 SEP 2020 20:27

PC Close Date & Time

23 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:58

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

23 SEP 2020 20:44

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:58

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

99.5 °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

24 SEP 2020 22:44

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:58

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

98.1 °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 SEP 2020 22:37

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:58

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

101.0 °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

26 SEP 2020 19:00

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:58

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	27 SEP 2020 12:33
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:58

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	28 SEP 2020 21:14
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	100.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	29 SEP 2020 17:33
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 12:10

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 17:04

PC Open Date & Time

22 SEP 2020 17:02

PC Close Date & Time

22 SEP 2020 19:32

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

22 SEP 2020 20:27

PC Close Date & Time

23 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:58

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

23 SEP 2020 20:46

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:58

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

24 SEP 2020 22:44

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:58

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

25 SEP 2020 22:38

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:58

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

26 SEP 2020 19:01

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:58

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

27 SEP 2020 12:33

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:58

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

28 SEP 2020 21:14

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 17:05
PC Open Date & Time	22 SEP 2020 17:02
PC Close Date & Time	22 SEP 2020 19:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 20:27

PC Close Date & Time

23 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:58

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 ☒

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:58

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 20:47
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:58

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 ☒

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:58

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 22:45
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:58

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 ☒

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:58

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 22:39
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:58

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 ☒

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:58

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 19:02
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:58

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 ☒

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:58

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 12:35
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:58

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 ☒

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:58

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 21:16
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

29 SEP 2020 17:34

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp

30 SEP 2020 12:10

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

29 SEP 2020 17:35

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

30 SEP 2020 12:11

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

01 OCT 2020 15:10

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

02 OCT 2020 12:36

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 04 OCT 2020 16:45

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

06 OCT 2020 16:45

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

07 OCT 2020 17:15

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

08 OCT 2020 12:35

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 09 OCT 2020 12:33

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

10 OCT 2020 12:00

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☒

Some interference with activity ☐
not requiring medical attention

Prevents daily activity and ☐
requires medical attention

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

PC Time stamp 29 SEP 2020 17:35

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☒

Some interference with activity ☐
not requiring medical attention

Prevents daily activity and ☐
requires medical attention

PC Open Date & Time	30 SEP 2020 12:00
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PC Close Date & Time	01 OCT 2020 11:59
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PC Time stamp	30 SEP 2020 12:11
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US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☒

Some interference with activity ☐
not requiring medical attention

Prevents daily activity and ☐
requires medical attention

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

PC Time stamp 01 OCT 2020 15:11

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☒

Some interference with activity ☐
not requiring medical attention

Prevents daily activity and ☐
requires medical attention

PC Open Date & Time	02 OCT 2020 12:00
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PC Close Date & Time	03 OCT 2020 11:59
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PC Time stamp	02 OCT 2020 12:36
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US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(12)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

PC Time stamp

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(13)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☒

Some interference with activity ☐
not requiring medical attention

Prevents daily activity and ☐
requires medical attention

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

PC Time stamp 04 OCT 2020 16:45

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(14)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

PC Time stamp

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(15)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

PC Time stamp 06 OCT 2020 16:45

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 SEP 2020 17:35
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 SEP 2020 12:11
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 10

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

No ☒

Yes ☐

PC Time stamp

01 OCT 2020 15:11

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 OCT 2020 12:36
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 12

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 13

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

No ☒

Yes ☐

PC Time stamp

04 OCT 2020 16:46

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 15

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

No ☒

Yes ☐

PC Time stamp

06 OCT 2020 16:45

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 OCT 2020 12:35
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 18

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

No ☒

Yes ☐

PC Time stamp

09 OCT 2020 12:34

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 OCT 2020 12:00
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3492237

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492237

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

DIAGNOSED WITH SARS-COV2

ON 28SEP2020, IN ILLNESS

If Contact Not Made, please provide Comments

TRACK

US3492237

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492237

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

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 VISIT2

US3492237

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input type="radio"/>
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="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3492237

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
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	

US3492237

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:58

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.

US3492237

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

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?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

Which arm was used to give treatment? Left Arm ☐
Right Arm ☐

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3492237

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

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/>

US3492237

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:43:58

Collection date (<i>dd MMM yyyy</i>)			
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

US3492237

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

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

US3492237

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

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

US3492237

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492237

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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	VISIT3

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 NOV 2020
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 14:55
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492237

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

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

US3492237

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 NOV 2020

Collection time (00:00-23:59)

15:05 (24 HR)

Collection date and time (derived)

23 NOV 2020 15:05

US3492237

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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	07 DEC 2020 10:46:02
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 12:21:57
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 DEC 2020 12:04:23
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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	28 DEC 2020 06:41:37
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

31 DEC 2020 07:19:10

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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	07 JAN 2021 06:07:35
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 06:47:12

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

25 JAN 2021 09:39:35

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

28 JAN 2021 14:23:45

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

04 FEB 2021 14:27:09

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 05:16:18

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 14:06:55

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	26 FEB 2021 06:08:56
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 14:26:42
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

11 MAR 2021 14:12:54

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

19 MAR 2021 12:24:39

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

25 MAR 2021 04:30:33

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

04 APR 2021 11:47:00

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 04:52:59

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 21:59:49

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 07:10:31

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 <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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 <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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 264

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

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

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

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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="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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 <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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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="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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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°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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 <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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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°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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 <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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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="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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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°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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 <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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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°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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 <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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐ Yes ☐

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

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 <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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 NOV 2022 00:01
Patient Cloud Close Date & Time	14 NOV 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

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

[Patient Cloud Open Date & Time](#)

24 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2022 23:59

US3492237

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:43:58

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		01 MAR 2021 04:53:05

US3492237

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492237

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492237

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:51:55

Generated On: 11 Aug 2021 22:43:58

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

US3492237

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:51:55

Generated On: 11 Aug 2021 22:43:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:51:55

Generated On: 11 Aug 2021 22:43:58

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

US3492237

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:51:55

Generated On: 11 Aug 2021 22:43:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 16:32:21

Generated On: 11 Aug 2021 22:43:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3492237

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 16:32:21

Generated On: 11 Aug 2021 22:43:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 APR 2021
Time of assessment (00:00-23:59)	15:04 (24 HR)
Vital Signs Date and Time (derived)	12 APR 2021 15:04
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492237

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 16:32:21

Generated On: 11 Aug 2021 22:43:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 APR 2021

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

US3492237

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 16:32:21

Generated On: 11 Aug 2021 22:43:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 APR 2021

Collection time (00:00-23:59)

15:13 (24 HR)

Collection date and time (derived)

12 APR 2021 15:13

US3492237

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 16:32:21

Generated On: 11 Aug 2021 22:43:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492237

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Date of Contact	27 SEP 2020
Time of Contact	12:00
Date and Time of Contact (derived)	27 SEP 2020 12:00
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>

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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"/>

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Symptom Day

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

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Symptom Day

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

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	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 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Symptom Day

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

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	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 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Symptom Day

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

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	100.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	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"/>

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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"/>

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	100.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Symptom Day

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

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	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"/>

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	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 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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"/>

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Symptom Day

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

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	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 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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

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

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Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 04:16:20

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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"/>

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Form: Symptom Log (11)

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 OCT 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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

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

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Form: Symptom Log (12)

Data signed: (b) (4) 15 Feb 2021 04:16:20

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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"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 OCT 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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

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

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Form: Symptom Log (13)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 15 Feb 2021 04:16:20

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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

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Form: Symptom Log (14)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Symptom Day

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

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Form: Symptom Log (14)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 OCT 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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

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

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Symptom Day

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

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	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)

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Symptom Day

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

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

	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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Date of Visit	28 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	28 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Feb 2021 04:16:20

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Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

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

Start Date

End Date

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 15 Feb 2021 04:16:21

Generated On: 11 Aug 2021 22:43:58

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	30 SEP 2020
Day 5	Yes	2 OCT 2020
Day 7	Yes	4 OCT 2020
Day 9	Yes	6 OCT 2020
Day 14	Yes	11 OCT 2020
Day 21	Yes	18 OCT 2020
Day 28	Yes	26 OCT 2020

US3492237

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:16:21

Generated On: 11 Aug 2021 22:43:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:16:21

Generated On: 11 Aug 2021 22:43:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	11:13 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 11:13
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	100.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492237

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:16:21

Generated On: 11 Aug 2021 22:43:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3492237

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 04:16:21

Generated On: 11 Aug 2021 22:43:58

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 SEP 2020

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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	SICKD28

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 15:10
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3492237

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 OCT 2020

US3492237

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:16:21

Generated On: 11 Aug 2021 22:43:58

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

Visit date (dd MMM yyyy)	28 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3492237

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 01:51:55

Generated On: 11 Aug 2021 22:43:58

Date of updated informed consent (<i>dd MMM yyyy</i>)	28 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	28 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3492237

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 04:16:49

Generated On: 11 Aug 2021 22:43:58

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3492237

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:16:49

Generated On: 11 Aug 2021 22:43:58

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	28 JAN 2021
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 14:55
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3492237

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:16:49

Generated On: 11 Aug 2021 22:43:58

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JAN 2021
Time of assessment (00:00-23:59)	15:54 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 15:54
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3492237

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

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:16:21

Generated On: 11 Aug 2021 22:43:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JAN 2021

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

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

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 01:51:55

Generated On: 11 Aug 2021 22:43:58

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 28 JAN 2021

What was the treatment time? (00:00-23:59) 15:50 (24 HR)

Treatment Date and Time (derived) 28 JAN 2021 15:50

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

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:16:21

Generated On: 11 Aug 2021 22:43:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JAN 2021

Collection time (00:00-23:59)

14:37 (24 HR)

Collection date and time (derived)

28 JAN 2021 14:37

US3492237

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 04:16:21

Generated On: 11 Aug 2021 22:43:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00 - 23:59)	14:45
Collection Date and Time (derived)	28 JAN 2021 14:45

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:16:21

Generated On: 11 Aug 2021 22:43:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:16:50

Generated On: 11 Aug 2021 22:43:58

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

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Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

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 _____

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Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

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)	

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Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:58

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.

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Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

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/>

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

AEID

Adverse event

HEADACHE

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)

24 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

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	PARTICIPANT CALLED TO REPORT 4 DAYS OF HEADACHE AND DIZZINESS, TOOK IBUPROFEN AND EXEDRIN WITH SOME RELIEF BUT THE SYMPTOMS RECURRED. HEADACHE IS DIFFERENT THAN HER USUAL MIGRAINES.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

AEID	USA-US101-2020-MRNA-1273-P30 1000002
Adverse event	COVID-19 INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	22 SEP 2020
Start time (00:00-23:59)	14:00 (24 HR)
AE start date and time (derived)	22 SEP 2020 14:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	9 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

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 checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

PARTICIPANT CALLED STUDY
STAFF ON 27SEP2020 TO REPORT
THAT HE HAS BEEN HAVING
SYMPTOMS OF A RESPIRATORY
INFECTION. HE RECEIVED HIS
FIRST DOSE OF IP ON 9/22, WAS
FINE UNTIL 9/24 WHEN HE
REPORTS CHILLS AND FELT
FEVERISH. HIS TEMP THAT
DAY WAS ABOUT 99. THE
FOLLOWING DAY HE
DEVELOPED HEADACHE,
CONTINUED WITH FEVER TO
101 AND CHILLS. YESTERDAY
9/26, HE DEVELOPED A
PRODUCTIVE COUGH, SCANTY
CLEAR SPUTUM. HE HAS BEEN
TAKING NAPROSYN DAILY
SINCE THE FEVERS BEGAN
WITH SOME RELIEF. NO
LOCALIZED INJECTION SITE
PAIN. NO SOB. HE HAS ASTHMA
AND CONTINUES TO USE HIS
INHALER. NO KNOWN SICK
CONTACTS ALTHOUGH HE
REPORTS HIS WIFE IS HAVING
A FLARE OF FIBROMYALGIA
AND HAS A LOW GRADE
FEVER.

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

AEID	
Adverse event	CHILLS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	24 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	06 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	22 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

Name of Medication ADVAIR

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 500-50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

Name of Medication MONTELUKAST

Prophylaxis Yes ☒
No ☐

Indication ASTHMA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

Name of Medication FLUTICASONE

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

Name of Medication AZELASTINE (0.1% - 137
MCG/SPRAY)

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 548

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication FEVER ASSOCIATED WITH
COVID INFECTION

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

	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 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 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"/>

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

	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)	01 JAN 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication MYALGIAS, ARTHRALGIAS
ASSOCIATED WITH COVID
INFECTION

Dose per administration 220

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

	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)		24 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

Name of Medication 2ND DOSE OF SHINGLES
VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication COUGH FROM COVID

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Feb 2021 04:16:19

Generated On: 11 Aug 2021 22:43:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	05 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	09 OCT 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

US3492237

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 04:16:20

Generated On: 11 Aug 2021 22:43:58

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3492237

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 15 Feb 2021 04:16:21

Generated On: 11 Aug 2021 22:43:58

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input checked="" type="checkbox"/>
	Visit 3 Day 57	<input type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

Case Report Form

Visit Date	True
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	True
Vital Signs - Dosing	True
Physical Examination	True
Central Laboratory - Nasopharyngeal Swab	True
Childbearing Potential	False
Pregnancy Test	False
Randomization	False
Exposure	True
Immunogenicity Assessment	True
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	True
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	False
Dosing Discontinuation	False

US3492237

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 15 Feb 2021 04:16:21

Generated On: 11 Aug 2021 22:43:58

End of Study / Study Discontinuation	False
All	False
Date of missed or out of window visit or assessment	27 OCT 2020
Category	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	False
Missed Visit	True
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	False
Other, specify	
Description of Relationship to COVID-19	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	True
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	False
Participant decision	True

US3492237

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 15 Feb 2021 04:16:21

Generated On: 11 Aug 2021 22:43:58

Date of dosing discontinuation (dd MMM yyyy) 28 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

US3492237

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:43:58

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 ☐

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 15 Feb 2021 04:16:49

Generated On: 11 Aug 2021 22:43:58

SAEID	USA-US101-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Feb 2021 04:16:49

Generated On: 11 Aug 2021 22:43:58

SAEID	USA-US101-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/OCT/2020 12:22
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

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Feb 2021 04:16:49

Generated On: 11 Aug 2021 22:43:58

SAEID	USA-US101-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	03/NOV/2020 00:00
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

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 15 Feb 2021 04:16:49

Generated On: 11 Aug 2021 22:43:58

SAEID	USA-US101-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	09/NOV/2020 13:26
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

US3492237 (Prod: UIC Project WISH CRS)

US3492237

Form: Participant Creation

Generated On: 11 Aug 2021 22:43:58

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'US3492237'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Sep 2020 20:10:25

US3492237

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:05:41

US3492237

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '22 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Sep 2020 20:10:26

US3492237

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[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 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:05:41

US3492237

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered 'SCRN'	System	22 Sep 2020 21:05:41

US3492237

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:58

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered (b) (6) 1960'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Sep 2020 20:10:27

US3492237

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:58

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '60'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:58

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered 'YEARS'	System	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:58

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered '60'	System	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:58

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:58

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:58

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:58

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:58

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:58

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:58

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:58

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:58

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:58

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:58

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:58

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered 'Sep 2020'	System	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered '2020'	System	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:58

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:58

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:58

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:58

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Sep 2020 20:10:26

US3492237

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:58

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered 'I'	System	22 Sep 2020 21:06:22

US3492237

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:06:22

US3492237

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:43:58

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	01 Nov 2020 21:41:18
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 21:07:13

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	01 Nov 2020 21:42:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Nov 2020 21:42:51
Data point term sent to Coder	System	01 Nov 2020 21:42:37
User entered 'Asthma-mild'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'UN UNK 1966'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered 'Jan 1966'	System	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered '1966'	System	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered empty.	System	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered empty.	System	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	01 Nov 2020 21:44:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Nov 2020 21:44:52
Data point term sent to Coder	System	01 Nov 2020 21:43:39
User entered 'Gastro-esophageal reflux disease'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:47

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'UN UNK 2018'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:47

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:47

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:47

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:47

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:47

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered 'Jan 2018'	System	01 Nov 2020 21:42:47

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered '2018'	System	01 Nov 2020 21:42:47

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered empty.	System	01 Nov 2020 21:42:47

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered empty.	System	01 Nov 2020 21:42:47

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4)	01 Nov 2020 21:45:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Nov 2020 21:45:52
Data point term sent to Coder	System	01 Nov 2020 21:44:40
User entered 'Allergic Rhinitis'	Andrea Wendrow (b) (4)	01 Nov 2020 21:44:36

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	Andrea Wendrow (b) (4)	01 Nov 2020 21:44:36

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'I'	Andrea Wendrow (b) (4)	01 Nov 2020 21:44:36

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	01 Nov 2020 21:44:36

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	Andrea Wendrow (b) (4)	01 Nov 2020 21:44:36

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	Andrea Wendrow (b) (4)	01 Nov 2020 21:44:36

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered empty.	System	01 Nov 2020 21:44:36

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered empty.	System	01 Nov 2020 21:44:36

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered empty.	System	01 Nov 2020 21:44:36

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered empty.	System	01 Nov 2020 21:44:36

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '15:50'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered '22 Sep 2020 15:50'	System	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '170' cm	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:07:54
DataPoint set to visible.	System	22 Sep 2020 21:06:22

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '103' kg	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:07:54
DataPoint set to visible.	System	22 Sep 2020 21:06:22

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered '35.64014'	System	22 Sep 2020 21:07:54
DataPoint set to visible.	System	22 Sep 2020 21:06:22

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered 'kg/m2'	System	22 Sep 2020 21:07:54
DataPoint set to visible.	System	22 Sep 2020 21:06:22

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered 'bpm'	System	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered 'breaths/min'	System	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered 'mmHg'	System	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User entered 'mmHg'	System	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

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[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32

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Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:04

US3492237

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:04

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

[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 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

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 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

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 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

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 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

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 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

[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 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

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 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

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 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

[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 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

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 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

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 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'airline employee'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

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 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

[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 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

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 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:08:33

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:09:00

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:09:00

US3492237

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:09:00

US3492237

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered 'VISIT1'	System	22 Sep 2020 21:09:00

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '22 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Sep 2020 21:00:37

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:58

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '115295'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Sep 2020 21:00:37

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:58

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Sep 2020 21:00:37

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:58

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)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:09:35

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:58

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)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:09:35

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:58

[Severe obesity \(body mass index > or = 40kg/m2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:09:35

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:58

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:09:35

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:58

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:09:35

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:58

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:09:35
DataPoint set to visible.	System	22 Sep 2020 21:06:17

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '15:50'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered '22 Sep 2020 15:50'	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '70'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered 'bpm'	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '16'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered 'breaths/min'	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '125'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered 'mmHg'	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '77'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered 'mmHg'	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 21:51:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	22 Sep 2020 21:51:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	22 Sep 2020 21:10:23
	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '22 Sep 2020' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	22 Sep 2020 21:51:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '16:52' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	22 Sep 2020 21:51:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered '22 Sep 2020 16:52'	System	22 Sep 2020 21:51:40
User entered empty.	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '36.6' C reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	22 Sep 2020 21:51:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 21:51:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Tympanic' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	22 Sep 2020 21:51:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '73' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	22 Sep 2020 21:51:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered 'bpm'	System	22 Sep 2020 21:51:40
User entered empty.	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '14' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 21:51:40
User entered empty.	Gizelle Alvarez (b) (4)	22 Sep 2020 21:10:23
	(b) (4)	
	(b) (4), (b) (6)	

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered 'breaths/min'	System	22 Sep 2020 21:51:40
User entered empty.	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '123' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	22 Sep 2020 21:51:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered 'mmHg'	System	22 Sep 2020 21:51:40
User entered empty.	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '79' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	22 Sep 2020 21:51:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered 'mmHg'	System	22 Sep 2020 21:51:40
User entered empty.	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:57

US3492237

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:10:57

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4)	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	22 Sep 2020 21:49:22

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

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)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	Gizelle Alvarez (b) (4)	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '22 Sep 2020'	Gizelle Alvarez (b) (4)	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '16:42'	(b) (4) Gizelle Alvarez (b) (4)	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered '22 Sep 2020 16:42'	System	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Left Arm (LEFT ARM)'	Gizelle Alvarez (b) (4)	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered 'ONCE'	System	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:27:31

US3492237

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:27:31

US3492237

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '15:58'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:27:31

US3492237

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered '22 Sep 2020 15:58'	System	22 Sep 2020 21:27:31

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:43:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '16:05'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered '22 Sep 2020 16:05'	System	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered empty.	System	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:28:30

US3492237

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered 'I'	System	22 Sep 2020 21:28:30

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:03:27', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'cf52e7df-f643-4de8-9584-7ffb5e75633a'	System	22 Sep 2020 22:03:54
User entered 'Yes (Y)'	System	22 Sep 2020 22:03:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:02:48', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'cf52e7df-f643-4de8-9584-7ffb5e75633a'	System	22 Sep 2020 22:03:54
User entered '97.9'	System	22 Sep 2020 22:03:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:03:10', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'cf52e7df-f643-4de8-9584-7ffb5e75633a'	System	22 Sep 2020 22:03:54
User entered 'No (N)'	System	22 Sep 2020 22:03:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:03:51', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'cf52e7df-f643-4de8-9584-7ffb5e75633a'	System	22 Sep 2020 22:03:54
User entered '22 Sep 2020 17:03'	System	22 Sep 2020 22:03:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '22 Sep 2020 17:02'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '22 Sep 2020 19:32'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '22 Sep 2020 20:27'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 2'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:43:36', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'f7f445f6-772a-4344-a4bd-7919b6b67453'	System	24 Sep 2020 01:45:01
User entered 'Yes (Y)'	System	24 Sep 2020 01:45:01

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:44:41', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'f7f445f6-772a-4344-a4bd-7919b6b67453'	System	24 Sep 2020 01:45:01
User entered '97.6'	System	24 Sep 2020 01:45:01

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:44:47', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'f7f445f6-772a-4344-a4bd-7919b6b67453'	System	24 Sep 2020 01:45:01
User entered 'No (N)'	System	24 Sep 2020 01:45:01

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:44:56', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'f7f445f6-772a-4344-a4bd-7919b6b67453'	System	24 Sep 2020 01:45:01
User entered '23 Sep 2020 20:44'	System	24 Sep 2020 01:45:01

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 3'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:43:14', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'bb1e124d-7648-46ba-ade9-d209194b4600'	System	25 Sep 2020 03:44:09
User entered 'Yes (Y)'	System	25 Sep 2020 03:44:09

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:43:35', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'bb1e124d-7648-46ba-ade9-d209194b4600'	System	25 Sep 2020 03:44:09
User entered '99.5'	System	25 Sep 2020 03:44:09

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:43:40', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'bb1e124d-7648-46ba-ade9-d209194b4600'	System	25 Sep 2020 03:44:09
User entered 'No (N)'	System	25 Sep 2020 03:44:09

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:44:03', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'bb1e124d-7648-46ba-ade9-d209194b4600'	System	25 Sep 2020 03:44:09
User entered '24 Sep 2020 22:44'	System	25 Sep 2020 03:44:09

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 4'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:37:38', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '7acfbde5-730b-4c1b-bfd2-cbbc7297becc'	System	26 Sep 2020 03:38:00
User entered 'Yes (Y)'	System	26 Sep 2020 03:38:00

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:37:46', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '7acfbde5-730b-4c1b-bfd2-cbbc7297becc'	System	26 Sep 2020 03:38:00
User entered '98.1'	System	26 Sep 2020 03:38:00

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:37:51', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '7acfbde5-730b-4c1b-bfd2-cbbc7297becc'	System	26 Sep 2020 03:38:00
User entered 'No (N)'	System	26 Sep 2020 03:38:00

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:37:56', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '7acfbde5-730b-4c1b-bfd2-cbbc7297becc'	System	26 Sep 2020 03:38:00
User entered '25 Sep 2020 22:37'	System	26 Sep 2020 03:38:00

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 5'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T18:59:32', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5397d17f-4e8d-4c4a-9322-5b37df25c678'	System	27 Sep 2020 00:00:26
User entered 'Yes (Y)'	System	27 Sep 2020 00:00:26

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:00:09', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5397d17f-4e8d-4c4a-9322-5b37df25c678'	System	27 Sep 2020 00:00:26
User entered '101.0'	System	27 Sep 2020 00:00:26

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:00:15', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5397d17f-4e8d-4c4a-9322-5b37df25c678'	System	27 Sep 2020 00:00:26
User entered 'No (N)'	System	27 Sep 2020 00:00:26

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:00:23', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5397d17f-4e8d-4c4a-9322-5b37df25c678'	System	27 Sep 2020 00:00:26
User entered '26 Sep 2020 19:00'	System	27 Sep 2020 00:00:26

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 6'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:31:48', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '73b8495a-f4db-4819-b13d-e9df944b5dca'	System	27 Sep 2020 17:33:05
User entered 'Yes (Y)'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:31:55', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '73b8495a-f4db-4819-b13d-e9df944b5dca'	System	27 Sep 2020 17:33:05
User entered '99.6'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:32:33', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '73b8495a-f4db-4819-b13d-e9df944b5dca'	System	27 Sep 2020 17:33:05
User entered 'Yes (Y)'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PAIN TYLENOL TO TREAT FEVER' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 07:33:31
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PAIN TYLENOL TO TREAT FEVER' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 18:06:57
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	27 Sep 2020 17:33:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:32:58', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '73b8495a-f4db-4819-b13d-e9df944b5dca'	System	27 Sep 2020 17:33:05
User entered '1'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:32:58', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '73b8495a-f4db-4819-b13d-e9df944b5dca'	System	27 Sep 2020 17:33:05
User entered '0'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:33:02', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '73b8495a-f4db-4819-b13d-e9df944b5dca'	System	27 Sep 2020 17:33:05
User entered '27 Sep 2020 12:33'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 7'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:13:20', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd5da1ff8-9eed-489d-a21a-e58e3759e7f6'	System	29 Sep 2020 02:14:31
User entered 'Yes (Y)'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:13:30', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd5da1ff8-9eed-489d-a21a-e58e3759e7f6'	System	29 Sep 2020 02:14:31
User entered '99.1'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:13:36', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd5da1ff8-9eed-489d-a21a-e58e3759e7f6'	System	29 Sep 2020 02:14:31
User entered 'Yes (Y)'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 11:52:30
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:13:46', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd5da1ff8-9eed-489d-a21a-e58e3759e7f6'	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:45
User entered '1'	System	29 Sep 2020 02:14:31
	System	29 Sep 2020 02:14:31
	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:13:46', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd5da1ff8-9eed-489d-a21a-e58e3759e7f6'	System	29 Sep 2020 02:14:31
User entered '0'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:14:26', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd5da1ff8-9eed-489d-a21a-e58e3759e7f6'	System	29 Sep 2020 02:14:31
User entered '28 Sep 2020 21:14'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	27 Sep 2020 17:33:05
User entered 'Day 8'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:43:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:33:17', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5d8e8144-66c6-4341-a5a5-4b219e4435f0'	System	29 Sep 2020 22:33:54
User entered 'Yes (Y)'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:43:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:33:29', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5d8e8144-66c6-4341-a5a5-4b219e4435f0' User entered '100.7'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:33:33', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5d8e8144-66c6-4341-a5a5-4b219e4435f0'	System	29 Sep 2020 22:33:54
User entered 'Yes (Y)'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 11:52:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:33:45', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5d8e8144-66c6-4341-a5a5-4b219e4435f0'	Andrea Wendrow (b) (4)	01 Oct 2020 21:18:01
User entered '1'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:43:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:33:45', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5d8e8144-66c6-4341-a5a5-4b219e4435f0'	System	29 Sep 2020 22:33:54
User entered '0'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:33:50', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5d8e8144-66c6-4341-a5a5-4b219e4435f0'	System	29 Sep 2020 22:33:54
User entered '29 Sep 2020 17:33'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	29 Sep 2020 02:14:31
User entered 'Day 9'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:43:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:10:26', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9a96acb4-c894-4a6c-889b-38c93520becf'	System	30 Sep 2020 17:10:46
User entered 'Yes (Y)'	System	30 Sep 2020 17:10:46

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:43:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:10:34', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9a96acb4-c894-4a6c-889b-38c93520becf' User entered '98.7'	System	30 Sep 2020 17:10:46

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:10:37', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9a96acb4-c894-4a6c-889b-38c93520becf'	System	30 Sep 2020 17:10:46
User entered 'No (N)'	System	30 Sep 2020 17:10:46

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:10:43', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9a96acb4-c894-4a6c-889b-38c93520becf'	System	30 Sep 2020 17:10:46
User entered '30 Sep 2020 12:10'	System	30 Sep 2020 17:10:46

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:04:08', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '22d7c567-708c-4282-846a-3d065345bdd8'	System	22 Sep 2020 22:04:37
User entered 'None (1)'	System	22 Sep 2020 22:04:37

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:04:12', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '22d7c567-708c-4282-846a-3d065345bdd8'	System	22 Sep 2020 22:04:37
User entered 'No (N)'	System	22 Sep 2020 22:04:37

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:04:16', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '22d7c567-708c-4282-846a-3d065345bdd8'	System	22 Sep 2020 22:04:37
User entered 'No (N)'	System	22 Sep 2020 22:04:37

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:04:26', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '22d7c567-708c-4282-846a-3d065345bdd8'	System	22 Sep 2020 22:04:37
User entered 'None (1)'	System	22 Sep 2020 22:04:37

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:04:32', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '22d7c567-708c-4282-846a-3d065345bdd8'	System	22 Sep 2020 22:04:37
User entered '22 Sep 2020 17:04'	System	22 Sep 2020 22:04:37

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '22 Sep 2020 17:02'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '22 Sep 2020 19:32'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '22 Sep 2020 20:27'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 2'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:45:29', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9bb89e9a-acef-45df-8aec-14b1aebd4176'	System	24 Sep 2020 01:46:33
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 01:46:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:45:42', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9bb89e9a-acef-45df-8aec-14b1aebd4176'	System	24 Sep 2020 01:46:33
User entered 'No (N)'	System	24 Sep 2020 01:46:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:46:12', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9bb89e9a-acef-45df-8aec-14b1aebd4176'	System	24 Sep 2020 01:46:33
User entered 'No (N)'	System	24 Sep 2020 01:46:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:46:19', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9bb89e9a-acef-45df-8aec-14b1aebd4176'	System	24 Sep 2020 01:46:33
User entered 'None (1)'	System	24 Sep 2020 01:46:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:46:27', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9bb89e9a-acef-45df-8aec-14b1aebd4176'	System	24 Sep 2020 01:46:33
User entered '23 Sep 2020 20:46'	System	24 Sep 2020 01:46:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 3'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:44:14', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '85674d51-9a16-4aa5-ae49-5acfb330d920'	System	25 Sep 2020 03:44:44
User entered 'None (1)'	System	25 Sep 2020 03:44:44

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:44:18', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '85674d51-9a16-4aa5-ae49-5acfb330d920'	System	25 Sep 2020 03:44:44
User entered 'No (N)'	System	25 Sep 2020 03:44:44

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:44:22', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '85674d51-9a16-4aa5-ae49-5acfb330d920'	System	25 Sep 2020 03:44:44
User entered 'No (N)'	System	25 Sep 2020 03:44:44

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:44:28', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '85674d51-9a16-4aa5-ae49-5acfb330d920'	System	25 Sep 2020 03:44:44
User entered 'None (1)'	System	25 Sep 2020 03:44:44

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:44:34', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '85674d51-9a16-4aa5-ae49-5acfb330d920'	System	25 Sep 2020 03:44:44
User entered '24 Sep 2020 22:44'	System	25 Sep 2020 03:44:44

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 4'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:38:09', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b42a28a4-6adf-4b62-aec4-be5ef0724ee2'	System	26 Sep 2020 03:38:33
User entered 'None (1)'	System	26 Sep 2020 03:38:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:38:14', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b42a28a4-6adf-4b62-aec4-be5ef0724ee2'	System	26 Sep 2020 03:38:33
User entered 'No (N)'	System	26 Sep 2020 03:38:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:38:18', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b42a28a4-6adf-4b62-aec4-be5ef0724ee2'	System	26 Sep 2020 03:38:33
User entered 'No (N)'	System	26 Sep 2020 03:38:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:38:22', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b42a28a4-6adf-4b62-aec4-be5ef0724ee2'	System	26 Sep 2020 03:38:33
User entered 'None (1)'	System	26 Sep 2020 03:38:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:38:27', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b42a28a4-6adf-4b62-aec4-be5ef0724ee2'	System	26 Sep 2020 03:38:33
User entered '25 Sep 2020 22:38'	System	26 Sep 2020 03:38:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 5'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:00:38', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a69c8a71-5d99-4189-8a84-d4f03e378851'	System	27 Sep 2020 00:01:11
User entered 'None (1)'	System	27 Sep 2020 00:01:11

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:00:43', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a69c8a71-5d99-4189-8a84-d4f03e378851'	System	27 Sep 2020 00:01:11
User entered 'No (N)'	System	27 Sep 2020 00:01:11

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:00:51', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a69c8a71-5d99-4189-8a84-d4f03e378851'	System	27 Sep 2020 00:01:11
User entered 'No (N)'	System	27 Sep 2020 00:01:11

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:01:02', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a69c8a71-5d99-4189-8a84-d4f03e378851'	System	27 Sep 2020 00:01:11
User entered 'None (1)'	System	27 Sep 2020 00:01:11

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:01:05', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a69c8a71-5d99-4189-8a84-d4f03e378851'	System	27 Sep 2020 00:01:11
User entered '26 Sep 2020 19:01'	System	27 Sep 2020 00:01:11

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 6'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:33:06', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a9084c10-7ed8-4c9f-951c-fd3ebfff5e90'	System	27 Sep 2020 17:33:35
User entered 'None (1)'	System	27 Sep 2020 17:33:35

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:33:10', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a9084c10-7ed8-4c9f-951c-fd3ebfff5e90'	System	27 Sep 2020 17:33:35
User entered 'No (N)'	System	27 Sep 2020 17:33:35

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:33:15', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a9084c10-7ed8-4c9f-951c-fd3ebfff5e90'	System	27 Sep 2020 17:33:35
User entered 'No (N)'	System	27 Sep 2020 17:33:35

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:33:20', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a9084c10-7ed8-4c9f-951c-fd3ebfff5e90'	System	27 Sep 2020 17:33:35
User entered 'None (1)'	System	27 Sep 2020 17:33:35

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:33:31', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a9084c10-7ed8-4c9f-951c-fd3ebfff5e90'	System	27 Sep 2020 17:33:35
User entered '27 Sep 2020 12:33'	System	27 Sep 2020 17:33:35

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 7'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:14:31', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'eba24a1a-6e29-425b-8fc2-859dde6957a5'	System	29 Sep 2020 02:14:49
User entered 'None (1)'	System	29 Sep 2020 02:14:49

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:14:34', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'eba24a1a-6e29-425b-8fc2-859dde6957a5'	System	29 Sep 2020 02:14:49
User entered 'No (N)'	System	29 Sep 2020 02:14:49

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:14:38', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'eba24a1a-6e29-425b-8fc2-859dde6957a5'	System	29 Sep 2020 02:14:49
User entered 'No (N)'	System	29 Sep 2020 02:14:49

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:14:42', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'eba24a1a-6e29-425b-8fc2-859dde6957a5'	System	29 Sep 2020 02:14:49
User entered 'None (1)'	System	29 Sep 2020 02:14:49

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:14:46', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'eba24a1a-6e29-425b-8fc2-859dde6957a5'	System	29 Sep 2020 02:14:49
User entered '28 Sep 2020 21:14'	System	29 Sep 2020 02:14:49

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:04:40', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '807e0443-6438-47ba-a2fc-65431e618f3d'	System	22 Sep 2020 22:05:32
User entered 'None (0)'	System	22 Sep 2020 22:05:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:04:59', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '807e0443-6438-47ba-a2fc-65431e618f3d'	System	22 Sep 2020 22:05:32
User entered 'No interference with activity (1)'	System	22 Sep 2020 22:05:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:05:04', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '807e0443-6438-47ba-a2fc-65431e618f3d'	System	22 Sep 2020 22:05:32
User entered 'None (0)'	System	22 Sep 2020 22:05:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:05:08', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '807e0443-6438-47ba-a2fc-65431e618f3d'	System	22 Sep 2020 22:05:32
User entered 'None (0)'	System	22 Sep 2020 22:05:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:05:11', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '807e0443-6438-47ba-a2fc-65431e618f3d'	System	22 Sep 2020 22:05:32
User entered 'None (0)'	System	22 Sep 2020 22:05:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:05:13', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '807e0443-6438-47ba-a2fc-65431e618f3d'	System	22 Sep 2020 22:05:32
User entered 'None (0)'	System	22 Sep 2020 22:05:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:05:23', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '807e0443-6438-47ba-a2fc-65431e618f3d'	System	22 Sep 2020 22:05:32
User entered 'No (N)'	System	22 Sep 2020 22:05:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:05:29', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '807e0443-6438-47ba-a2fc-65431e618f3d'	System	22 Sep 2020 22:05:32
User entered '22 Sep 2020 17:05'	System	22 Sep 2020 22:05:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '22 Sep 2020 17:02'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '22 Sep 2020 19:32'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '22 Sep 2020 20:27'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 2'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:46:40', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '64c5bebf-387b-4c02-902c-c7d72d3e4bca'	System	24 Sep 2020 01:47:25
User entered 'None (0)'	System	24 Sep 2020 01:47:25

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:46:44', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '64c5bebf-387b-4c02-902c-c7d72d3e4bca'	System	24 Sep 2020 01:47:25
User entered 'None (0)'	System	24 Sep 2020 01:47:25

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:46:49', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '64c5bebf-387b-4c02-902c-c7d72d3e4bca'	System	24 Sep 2020 01:47:25
User entered 'None (0)'	System	24 Sep 2020 01:47:25

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:47:06', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '64c5bebf-387b-4c02-902c-c7d72d3e4bca'	System	24 Sep 2020 01:47:25
User entered 'None (0)'	System	24 Sep 2020 01:47:25

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:47:10', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '64c5bebf-387b-4c02-902c-c7d72d3e4bca'	System	24 Sep 2020 01:47:25
User entered 'None (0)'	System	24 Sep 2020 01:47:25

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:47:12', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '64c5bebf-387b-4c02-902c-c7d72d3e4bca'	System	24 Sep 2020 01:47:25
User entered 'None (0)'	System	24 Sep 2020 01:47:25

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:47:19', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '64c5bebf-387b-4c02-902c-c7d72d3e4bca'	System	24 Sep 2020 01:47:25
User entered 'No (N)'	System	24 Sep 2020 01:47:25

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:47:22', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '64c5bebf-387b-4c02-902c-c7d72d3e4bca'	System	24 Sep 2020 01:47:25
User entered '23 Sep 2020 20:47'	System	24 Sep 2020 01:47:25

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 3'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:44:46', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'ab524855-ddf7-49c0-9c40-eba719d6f344'	System	25 Sep 2020 03:45:57
User entered 'No interference with activity (1)'	System	25 Sep 2020 03:45:57

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:45:16', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'ab524855-ddf7-49c0-9c40-eba719d6f344'	System	25 Sep 2020 03:45:57
User entered 'Some interference with activity (2)'	System	25 Sep 2020 03:45:57

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:45:21', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'ab524855-ddf7-49c0-9c40-eba719d6f344'	System	25 Sep 2020 03:45:57
User entered 'No interference with activity (1)'	System	25 Sep 2020 03:45:57

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:45:30', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'ab524855-ddf7-49c0-9c40-eba719d6f344'	System	25 Sep 2020 03:45:57
User entered 'No interference with activity (1)'	System	25 Sep 2020 03:45:57

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:45:37', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'ab524855-ddf7-49c0-9c40-eba719d6f344'	System	25 Sep 2020 03:45:57
User entered 'None (0)'	System	25 Sep 2020 03:45:57

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:45:42', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'ab524855-ddf7-49c0-9c40-eba719d6f344'	System	25 Sep 2020 03:45:57
User entered 'Some interference with activity not requiring medical attention (2)'	System	25 Sep 2020 03:45:57

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:45:48', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'ab524855-ddf7-49c0-9c40-eba719d6f344'	System	25 Sep 2020 03:45:57
User entered 'No (N)'	System	25 Sep 2020 03:45:57

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:45:55', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'ab524855-ddf7-49c0-9c40-eba719d6f344'	System	25 Sep 2020 03:45:57
User entered '24 Sep 2020 22:45'	System	25 Sep 2020 03:45:57

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 4'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:38:40', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '36263254-f41c-49e9-9ff2-e3a39295982e' User entered 'None (0)'	System	26 Sep 2020 03:39:26
	System	26 Sep 2020 03:39:26

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:38:53', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '36263254-f41c-49e9-9ff2-e3a39295982e'	System	26 Sep 2020 03:39:26
User entered 'No interference with activity (1)'	System	26 Sep 2020 03:39:26

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:38:56', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '36263254-f41c-49e9-9ff2-e3a39295982e' User entered 'None (0)'	System	26 Sep 2020 03:39:26
	System	26 Sep 2020 03:39:26

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:39:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '36263254-f41c-49e9-9ff2-e3a39295982e' User entered 'None (0)'	System	26 Sep 2020 03:39:26

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:39:03', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '36263254-f41c-49e9-9ff2-e3a39295982e' User entered 'None (0)'	System	26 Sep 2020 03:39:26
	System	26 Sep 2020 03:39:26

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:39:13', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '36263254-f41c-49e9-9ff2-e3a39295982e'	System	26 Sep 2020 03:39:26
User entered 'No interference with activity (1)'	System	26 Sep 2020 03:39:26

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:39:19', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '36263254-f41c-49e9-9ff2-e3a39295982e'	System	26 Sep 2020 03:39:26
User entered 'No (N)'	System	26 Sep 2020 03:39:26

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:39:22', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '36263254-f41c-49e9-9ff2-e3a39295982e'	System	26 Sep 2020 03:39:26
User entered '25 Sep 2020 22:39'	System	26 Sep 2020 03:39:26

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 5'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:01:26', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '68a54175-b01d-4162-998a-96e1afbf6dda'	System	27 Sep 2020 00:02:47
User entered 'None (0)'	System	27 Sep 2020 00:02:47

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:01:36', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '68a54175-b01d-4162-998a-96e1afbf6dda'	System	27 Sep 2020 00:02:47
User entered 'No interference with activity (1)'	System	27 Sep 2020 00:02:47

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:01:45', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '68a54175-b01d-4162-998a-96e1afbf6dda' User entered 'None (0)'	System	27 Sep 2020 00:02:47
	System	27 Sep 2020 00:02:47

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:01:49', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '68a54175-b01d-4162-998a-96e1afbf6dda' User entered 'None (0)'	System	27 Sep 2020 00:02:47

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:01:53', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '68a54175-b01d-4162-998a-96e1afbf6dda' User entered 'None (0)'	System	27 Sep 2020 00:02:47
	System	27 Sep 2020 00:02:47

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:02:29', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '68a54175-b01d-4162-998a-96e1afbf6dda'	System	27 Sep 2020 00:02:47
User entered 'No interference with activity (1)'	System	27 Sep 2020 00:02:47

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:02:36', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '68a54175-b01d-4162-998a-96e1afbf6dda'	System	27 Sep 2020 00:02:47
User entered 'No (N)'	System	27 Sep 2020 00:02:47

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:02:41', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '68a54175-b01d-4162-998a-96e1afbf6dda'	System	27 Sep 2020 00:02:47
User entered '26 Sep 2020 19:02'	System	27 Sep 2020 00:02:47

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 6'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:33:48', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '399cecfb-d7a4-4e40-b3f2-2d54d5305291'	System	27 Sep 2020 17:35:49
User entered 'No interference with activity (1)'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:34:19', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '399cecfb-d7a4-4e40-b3f2-2d54d5305291'	System	27 Sep 2020 17:35:49
User entered 'No interference with activity (1)'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:34:45', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '399cecfb-d7a4-4e40-b3f2-2d54d5305291'	System	27 Sep 2020 17:35:49
User entered 'None (0)'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:34:51', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '399cecfb-d7a4-4e40-b3f2-2d54d5305291'	System	27 Sep 2020 17:35:49
User entered 'None (0)'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:34:55', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '399cecfb-d7a4-4e40-b3f2-2d54d5305291'	System	27 Sep 2020 17:35:49
User entered 'None (0)'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:34:59', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '399cecfb-d7a4-4e40-b3f2-2d54d5305291'	System	27 Sep 2020 17:35:49
User entered 'No interference with activity (1)'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:35:43', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '399cecfb-d7a4-4e40-b3f2-2d54d5305291'	System	27 Sep 2020 17:35:49
User entered 'No (N)'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:35:46', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '399cecfb-d7a4-4e40-b3f2-2d54d5305291'	System	27 Sep 2020 17:35:49
User entered '27 Sep 2020 12:35'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 7'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:14:59', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4f78b8a-5940-4bfa-b7d0-159f9c3d88fe'	System	29 Sep 2020 02:16:49
User entered 'No interference with activity (1)'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:15:05', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4f78b8a-5940-4bfa-b7d0-159f9c3d88fe'	System	29 Sep 2020 02:16:49
User entered 'No interference with activity (1)'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:15:08', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4f78b8a-5940-4bfa-b7d0-159f9c3d88fe' User entered 'None (0)'	System	29 Sep 2020 02:16:49
	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:16:30', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4f78b8a-5940-4bfa-b7d0-159f9c3d88fe'	System	29 Sep 2020 02:16:49
User entered 'None (0)'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:16:33', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4f78b8a-5940-4bfa-b7d0-159f9c3d88fe' User entered 'None (0)'	System	29 Sep 2020 02:16:49
	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:16:38', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4f78b8a-5940-4bfa-b7d0-159f9c3d88fe'	System	29 Sep 2020 02:16:49
User entered 'No interference with activity (1)'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:16:43', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4f78b8a-5940-4bfa-b7d0-159f9c3d88fe'	System	29 Sep 2020 02:16:49
User entered 'No (N)'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:16:46', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4f78b8a-5940-4bfa-b7d0-159f9c3d88fe'	System	29 Sep 2020 02:16:49
User entered '28 Sep 2020 21:16'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	27 Sep 2020 17:35:49
User entered 'Day 8'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:34:52', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '606ed0b5-fa94-4615-a254-14cf4ee10388'	System	29 Sep 2020 22:34:59
User entered 'No interference with activity (1)'	System	29 Sep 2020 22:34:59

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:34:55', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '606ed0b5-fa94-4615-a254-14cf4ee10388'	System	29 Sep 2020 22:34:59
User entered '29 Sep 2020 17:34'	System	29 Sep 2020 22:34:59

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	29 Sep 2020 02:16:49
User entered 'Day 9'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:10:48', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '6d7f1f4c-307f-4e35-aecf-ff804e693e72'	System	30 Sep 2020 17:10:53
User entered 'None (0)'	System	30 Sep 2020 17:10:53

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:10:51', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '6d7f1f4c-307f-4e35-aecf-ff804e693e72'	System	30 Sep 2020 17:10:53
User entered '30 Sep 2020 12:10'	System	30 Sep 2020 17:10:53

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	27 Sep 2020 17:35:49
User entered 'Day 8'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:35:02', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd65e3d3d-9d56-4ddc-b47f-e229dceb76c2'	System	29 Sep 2020 22:35:11
User entered 'No interference with activity (1)'	System	29 Sep 2020 22:35:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:35:09', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd65e3d3d-9d56-4ddc-b47f-e229dceb76c2'	System	29 Sep 2020 22:35:11
User entered '29 Sep 2020 17:35'	System	29 Sep 2020 22:35:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	29 Sep 2020 02:16:49
User entered 'Day 9'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:10:57', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a42ae5f9-c607-4efb-a49c-2f659eb5c2ab'	System	30 Sep 2020 17:11:11
User entered 'No interference with activity (1)'	System	30 Sep 2020 17:11:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:11:07', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a42ae5f9-c607-4efb-a49c-2f659eb5c2ab'	System	30 Sep 2020 17:11:11
User entered '30 Sep 2020 12:11'	System	30 Sep 2020 17:11:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	29 Sep 2020 22:35:11
User entered 'Day 10'	System	29 Sep 2020 22:35:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-01T15:10:55', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '141c4fb4-c7ae-4944-aaab-1b88dbd8acb9'	System	01 Oct 2020 20:11:04
User entered 'Some interference with activity (2)'	System	01 Oct 2020 20:11:04

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-01T15:10:58', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '141c4fb4-c7ae-4944-aaab-1b88dbd8acb9'	System	01 Oct 2020 20:11:04
User entered '01 Oct 2020 15:10'	System	01 Oct 2020 20:11:04

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 22:35:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 22:35:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	30 Sep 2020 17:11:11
User entered 'Day 11'	System	30 Sep 2020 17:11:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-02T12:35:56', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'eda62ece-1454-46c0-9e4c-ae14c402cc26'	System	02 Oct 2020 17:36:09
User entered 'Some interference with activity (2)'	System	02 Oct 2020 17:36:09

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-02T12:36:01', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'eda62ece-1454-46c0-9e4c-ae14c402cc26'	System	02 Oct 2020 17:36:09
User entered '02 Oct 2020 12:36'	System	02 Oct 2020 17:36:09

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:11:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:11:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	01 Oct 2020 20:11:04
User entered 'Day 12'	System	01 Oct 2020 20:11:04

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 20:11:04

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 20:11:04

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	02 Oct 2020 17:36:09
User entered 'Day 13'	System	02 Oct 2020 17:36:09

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-04T16:45:32', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '98aff5dd-e55b-4dba-a870-4a1ea51063a2'	System	04 Oct 2020 21:45:41
User entered 'No interference with activity (1)'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-04T16:45:37', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '98aff5dd-e55b-4dba-a870-4a1ea51063a2'	System	04 Oct 2020 21:45:41
User entered '04 Oct 2020 16:45'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:36:09

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:36:09

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	04 Oct 2020 21:45:41
User entered 'Day 14'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	04 Oct 2020 21:45:41
User entered 'Day 15'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-06T16:44:57', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '249b42b2-20c0-4459-bd83-e6e6ecd2a076'	System	06 Oct 2020 21:45:07
User entered 'Some interference with activity (2)'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-06T16:45:01', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '249b42b2-20c0-4459-bd83-e6e6ecd2a076' User entered '06 Oct 2020 16:45'	System	06 Oct 2020 21:45:07
	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	06 Oct 2020 21:45:07
User entered 'Day 16'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-07T17:15:25', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9c030b90-ebbe-49ce-bd22-1bd7596c2143'	System	07 Oct 2020 22:15:31
User entered 'No interference with activity (1)'	System	07 Oct 2020 22:15:31

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-07T17:15:28', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9c030b90-ebbe-49ce-bd22-1bd7596c2143'	System	07 Oct 2020 22:15:31
User entered '07 Oct 2020 17:15'	System	07 Oct 2020 22:15:31

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	06 Oct 2020 21:45:07
User entered 'Day 17'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-08T12:35:17', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '59d7c286-6ecf-4893-a895-0405883ac43e'	System	08 Oct 2020 17:35:23
User entered 'No interference with activity (1)'	System	08 Oct 2020 17:35:23

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-08T12:35:20', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '59d7c286-6ecf-4893-a895-0405883ac43e'	System	08 Oct 2020 17:35:23
User entered '08 Oct 2020 12:35'	System	08 Oct 2020 17:35:23

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	07 Oct 2020 22:15:31
User entered 'Day 18'	System	07 Oct 2020 22:15:31

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-09T12:33:50', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '647c2d38-11bd-441e-8686-e3eabf371887'	System	09 Oct 2020 17:34:00
User entered 'No interference with activity (1)'	System	09 Oct 2020 17:34:00

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-09T12:33:53', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '647c2d38-11bd-441e-8686-e3eabf371887' User entered '09 Oct 2020 12:33'	System	09 Oct 2020 17:34:00
	System	09 Oct 2020 17:34:00

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 22:15:31

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 22:15:31

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	08 Oct 2020 17:35:23
User entered 'Day 19'	System	08 Oct 2020 17:35:23

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-10T12:00:30', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a178de0e-e7f6-4bb5-9ed2-3fb57d05a2fb'	System	10 Oct 2020 17:00:42
User entered 'None (0)'	System	10 Oct 2020 17:00:42

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 11 Aug 2021 22:43:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-10T12:00:33', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a178de0e-e7f6-4bb5-9ed2-3fb57d05a2fb'	System	10 Oct 2020 17:00:42
User entered '10 Oct 2020 12:00'	System	10 Oct 2020 17:00:42

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 17:35:23

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 17:35:23

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	27 Sep 2020 17:35:49
User entered 'Day 8'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:35:14', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '7a5737b4-3f3b-40a0-b219-ada6f0d13574'	System	29 Sep 2020 22:35:20
User entered 'No interference with activity (1)'	System	29 Sep 2020 22:35:20

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:35:16', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '7a5737b4-3f3b-40a0-b219-ada6f0d13574'	System	29 Sep 2020 22:35:20
User entered '29 Sep 2020 17:35'	System	29 Sep 2020 22:35:20

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	29 Sep 2020 02:16:49
User entered 'Day 9'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:11:15', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'c0770885-b463-474b-8082-3a3abc49ac6d'	System	30 Sep 2020 17:11:26
User entered 'No interference with activity (1)'	System	30 Sep 2020 17:11:26

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:11:20', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'c0770885-b463-474b-8082-3a3abc49ac6d'	System	30 Sep 2020 17:11:26
User entered '30 Sep 2020 12:11'	System	30 Sep 2020 17:11:26

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	29 Sep 2020 22:35:20
User entered 'Day 10'	System	29 Sep 2020 22:35:20

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-01T15:11:03', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '690ad48b-3bf8-4176-9b3e-d2a664cd26d9'	System	01 Oct 2020 20:11:09
User entered 'No interference with activity (1)'	System	01 Oct 2020 20:11:09

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 22:35:20

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 22:35:20

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-01T15:11:06', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '690ad48b-3bf8-4176-9b3e-d2a664cd26d9'	System	01 Oct 2020 20:11:09
User entered '01 Oct 2020 15:11'	System	01 Oct 2020 20:11:09

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	30 Sep 2020 17:11:26
User entered 'Day 11'	System	30 Sep 2020 17:11:26

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-02T12:36:07', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '69ef85fe-a0fd-4626-9235-f18a8bba1701'	System	02 Oct 2020 17:36:15
User entered 'No interference with activity (1)'	System	02 Oct 2020 17:36:15

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:11:26

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:11:26

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-02T12:36:11', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '69ef85fe-a0fd-4626-9235-f18a8bba1701'	System	02 Oct 2020 17:36:15
User entered '02 Oct 2020 12:36'	System	02 Oct 2020 17:36:15

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(12)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	01 Oct 2020 20:11:09
User entered 'Day 12'	System	01 Oct 2020 20:11:09

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(12)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(12)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 20:11:09

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(12)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 20:11:09

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(12)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(13)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	02 Oct 2020 17:36:15
User entered 'Day 13'	System	02 Oct 2020 17:36:15

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(13)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-04T16:45:49', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'db045ebe-eb99-4afa-914c-df4cd8db3846'	System	04 Oct 2020 21:45:56
User entered 'No interference with activity (1)'	System	04 Oct 2020 21:45:56

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(13)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:36:15

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(13)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:36:15

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(13)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-04T16:45:51', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'db045ebe-eb99-4afa-914c-df4cd8db3846'	System	04 Oct 2020 21:45:56
User entered '04 Oct 2020 16:45'	System	04 Oct 2020 21:45:56

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(14)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	04 Oct 2020 21:45:56
User entered 'Day 14'	System	04 Oct 2020 21:45:56

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(14)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(14)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 21:45:56

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(14)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 21:45:56

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(14)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(15)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	04 Oct 2020 21:45:56
User entered 'Day 15'	System	04 Oct 2020 21:45:56

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(15)

Generated On: 11 Aug 2021 22:43:58

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-06T16:45:06', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '54e8a2ef-c068-4bfd-989a-d5c61fe17cf3'	System	06 Oct 2020 21:45:14
User entered 'None (0)'	System	06 Oct 2020 21:45:14

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(15)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 21:45:56

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(15)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 21:45:56

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(15)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-06T16:45:08', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '54e8a2ef-c068-4bfd-989a-d5c61fe17cf3'	System	06 Oct 2020 21:45:14
User entered '06 Oct 2020 16:45'	System	06 Oct 2020 21:45:14

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	27 Sep 2020 17:33:05
User entered 'Day 8'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:35:25', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '32885fda-990c-452a-a73a-247ec252f7ac'	System	29 Sep 2020 22:35:33
User entered 'No (N)'	System	29 Sep 2020 22:35:33

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:35:27', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '32885fda-990c-452a-a73a-247ec252f7ac'	System	29 Sep 2020 22:35:33
User entered '29 Sep 2020 17:35'	System	29 Sep 2020 22:35:33

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	29 Sep 2020 02:14:31
User entered 'Day 9'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:11:26', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '4d9161e0-d81a-44b8-b445-2b698d1f5a50'	System	30 Sep 2020 17:11:34
User entered 'No (N)'	System	30 Sep 2020 17:11:34

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:11:28', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '4d9161e0-d81a-44b8-b445-2b698d1f5a50'	System	30 Sep 2020 17:11:34
User entered '30 Sep 2020 12:11'	System	30 Sep 2020 17:11:34

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	29 Sep 2020 22:33:54
User entered 'Day 10'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-01T15:11:16', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '7127d8ad-8198-415c-904b-6957742ea226'	System	01 Oct 2020 20:11:27
User entered 'No (N)'	System	01 Oct 2020 20:11:27

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-01T15:11:22', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '7127d8ad-8198-415c-904b-6957742ea226'	System	01 Oct 2020 20:11:27
User entered '01 Oct 2020 15:11'	System	01 Oct 2020 20:11:27

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	30 Sep 2020 17:11:11
User entered 'Day 11'	System	30 Sep 2020 17:11:11

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-02T12:36:17', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '08f07d7a-6efa-4c01-bbae-1da74fd88e17'	System	02 Oct 2020 17:36:25
User entered 'No (N)'	System	02 Oct 2020 17:36:25

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-02T12:36:20', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '08f07d7a-6efa-4c01-bbae-1da74fd88e17'	System	02 Oct 2020 17:36:25
User entered '02 Oct 2020 12:36'	System	02 Oct 2020 17:36:25

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:11:11

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:11:11

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	01 Oct 2020 20:11:04
User entered 'Day 12'	System	01 Oct 2020 20:11:04

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 20:11:04

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 20:11:04

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	02 Oct 2020 17:36:09
User entered 'Day 13'	System	02 Oct 2020 17:36:09

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-04T16:45:57', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'c0c3dbb2-8809-49dd-ab8c-b2777e60e21c'	System	04 Oct 2020 21:46:06
User entered 'No (N)'	System	04 Oct 2020 21:46:06

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-04T16:46:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'c0c3dbb2-8809-49dd-ab8c-b2777e60e21c'	System	04 Oct 2020 21:46:06
User entered '04 Oct 2020 16:46'	System	04 Oct 2020 21:46:06

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:36:09

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:36:09

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	04 Oct 2020 21:45:41
User entered 'Day 14'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	04 Oct 2020 21:45:41
User entered 'Day 15'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-06T16:45:14', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '56217953-3ba0-4760-8c87-905a510973d7'	System	06 Oct 2020 21:45:25
User entered 'No (N)'	System	06 Oct 2020 21:45:25

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-06T16:45:17', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '56217953-3ba0-4760-8c87-905a510973d7' User entered '06 Oct 2020 16:45'	System	06 Oct 2020 21:45:25
	System	06 Oct 2020 21:45:25

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	06 Oct 2020 21:45:07
User entered 'Day 17'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-08T12:35:26', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '3b9d0d1c-981d-4463-aa3f-61b9e8061a1b'	System	08 Oct 2020 17:35:31
User entered 'No (N)'	System	08 Oct 2020 17:35:31

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-08T12:35:28', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '3b9d0d1c-981d-4463-aa3f-61b9e8061a1b'	System	08 Oct 2020 17:35:31
User entered '08 Oct 2020 12:35'	System	08 Oct 2020 17:35:31

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	07 Oct 2020 22:15:31
User entered 'Day 18'	System	07 Oct 2020 22:15:31

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-09T12:34:06', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '89f6fea5-02e5-48b2-8fe6-acfcf33ba315'	System	09 Oct 2020 17:34:16
User entered 'No (N)'	System	09 Oct 2020 17:34:16

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-09T12:34:14', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '89f6fea5-02e5-48b2-8fe6-acfcf33ba315'	System	09 Oct 2020 17:34:16
User entered '09 Oct 2020 12:34'	System	09 Oct 2020 17:34:16

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 22:15:31

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 22:15:31

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
Data entry locked.	System	08 Oct 2020 17:35:23
User entered 'Day 19'	System	08 Oct 2020 17:35:23

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:43:58

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)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-10T12:00:37', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '4b7854ca-7deb-4d92-9050-d292fe6271f0'	System	10 Oct 2020 17:00:47
User entered 'No (N)'	System	10 Oct 2020 17:00:47

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:43:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-10T12:00:39', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '4b7854ca-7deb-4d92-9050-d292fe6271f0'	System	10 Oct 2020 17:00:47
User entered '10 Oct 2020 12:00'	System	10 Oct 2020 17:00:47

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:43:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 17:35:23

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:43:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:28
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 17:35:23

US3492237

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	Addis Mekonnen (b) (4)	30 Sep 2020 17:29:58

US3492237

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '30 Sep 2020'	Addis Mekonnen (b) (4)	30 Sep 2020 17:29:58

US3492237

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Addis Mekonnen (b) (4)	30 Sep 2020 17:29:58

US3492237

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	Addis Mekonnen (b) (4)	30 Sep 2020 17:29:58

US3492237

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	Addis Mekonnen (b) (4)	30 Sep 2020 17:30:03

US3492237

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered 'I'	System	30 Sep 2020 17:30:03

US3492237

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	12 Oct 2020 05:13:25

US3492237

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	12 Oct 2020 05:13:25

US3492237

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	12 Oct 2020 05:13:25

US3492237

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'diagnosed with SARS-CoV2 on 28Sep2020, in illness track'	(b) (4) Andrea Wendrow (b) (4)	12 Oct 2020 05:13:25

US3492237

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	12 Oct 2020 05:13:35

US3492237

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:08
User entered 'I'	System	12 Oct 2020 05:13:35

US3492237

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:59:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:43:45

US3492237

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:59:07
User entered 'I'	System	05 Nov 2020 15:43:45

US3492237

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User closed query 'Per CDM: Please complete the Exposure form under Visit 2 folder.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:22:35
Query 'Per CDM: Please complete the Exposure form under Visit 2 folder.' answered with '-----Completed. Thank You.-----' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 16:36:49
User opened query 'Per CDM: Please complete the Exposure form under Visit 2 folder.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 08:57:47
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	06 Nov 2020 15:06:24

US3492237

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	Lorna Sanchez McCann (b) (4)	06 Nov 2020 15:06:24

US3492237

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) Lorna Sanchez McCann	06 Nov 2020 15:06:24
	(b) (4)	

US3492237

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered 'VISIT2'	System	06 Nov 2020 15:06:24

US3492237

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:36:17

US3492237

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Confirmed COVID-19 (COVID)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:36:17

US3492237

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:36:17

US3492237

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered empty.	System	21 Jan 2021 16:36:17

US3492237

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:36:17

US3492237

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:36:17

US3492237

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered empty.	System	21 Jan 2021 16:36:17

US3492237

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:36:17

US3492237

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered empty.	System	21 Jan 2021 16:36:17

US3492237

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered empty.	System	21 Jan 2021 16:36:17

US3492237

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User closed query 'Per CDM: Visit Page for Visit 2 Day 29 has not been completed. Please complete the Visit Date page and provide a YES or NO response to 'Was this visit performed?'. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 10:10:48
Query 'Per CDM: Visit Page for Visit 2 Day 29 has not been completed. Please complete the Visit Date page and provide a YES or NO response to 'Was this visit performed?'. ' answered with 'updated ' (Site from DM).	Lorna Sanchez McCann (b) (4)	06 Nov 2020 15:08:35
User opened query 'Per CDM: Visit Page for Visit 2 Day 29 has not been completed. Please complete the Visit Date page and provide a YES or NO response to 'Was this visit performed?'. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:15:05
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:44:00

US3492237

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered 'I'	System	05 Nov 2020 15:44:00

US3492237

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:44:10

US3492237

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '2 Nov 2020'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:44:10

US3492237

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Contact Made (CONTACT MADE)'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:44:10

US3492237

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:44:10

US3492237

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	05 Nov 2020 15:44:32
	(b) (4)	

US3492237

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered 'I'	System	05 Nov 2020 15:44:32

US3492237

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:21:27

US3492237

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '9 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:21:27

US3492237

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:21:27

US3492237

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:21:27

US3492237

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:21:33

US3492237

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered 'I'	System	10 Nov 2020 18:21:33

US3492237

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	18 Nov 2020 16:29:50

US3492237

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '16 Nov 2020'	Nusirat Williams (b) (4)	18 Nov 2020 16:29:50

US3492237

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:29:50

US3492237

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	Nusirat Williams (b) (4)	18 Nov 2020 16:29:50

US3492237

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:29:57

US3492237

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered 'I'	System	18 Nov 2020 16:29:57

US3492237

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	23 Nov 2020 21:03:31
	(b) (4)	

US3492237

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '23 Nov 2020'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:03:31

US3492237

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Clinic (Clinic)'	(b) (4) Lorna Sanchez McCann	23 Nov 2020 21:03:31
	(b) (4)	

US3492237

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered 'VISIT3'	System	23 Nov 2020 21:03:31

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '23 Nov 2020'	(b) (4) Lorna Sanchez McCann	23 Nov 2020 21:08:00
	(b) (4)	

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '14:55'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered '23 Nov 2020 14:55'	System	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 04:08:43
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:10
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	23 Nov 2020 21:08:00
User entered '96.5' F	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Other (Other)'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'tympanic'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '72'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered 'bpm'	System	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '18'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered 'breaths/min'	System	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '125'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered 'mmHg'	System	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '69'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered 'mmHg'	System	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53

US3492237

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	23 Nov 2020 21:08:30
	(b) (4)	

US3492237

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '23 Nov 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:30

US3492237

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	23 Nov 2020 21:08:24
	(b) (4)	

US3492237

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '23 Nov 2020'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:24

US3492237

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '15:05'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:24

US3492237

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered '23 Nov 2020 15:05'	System	23 Nov 2020 21:08:24

US3492237

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	23 Nov 2020 21:08:33
	(b) (4)	

US3492237

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:28:53
User entered 'I'	System	23 Nov 2020 21:08:33

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2020-12-07T10:45:54', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'cb1a98f7-7b1b-4538-8d05-faaf548d5c5b'	System	07 Dec 2020 16:46:08
User entered 'No (N)'	System	07 Dec 2020 16:46:08

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2020-12-07T10:46:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'cb1a98f7-7b1b-4538-8d05-faaf548d5c5b'	System	07 Dec 2020 16:46:08
User entered 'No (N)'	System	07 Dec 2020 16:46:08

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-12-07T10:46:02', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'cb1a98f7-7b1b-4538-8d05-faaf548d5c5b'	System	07 Dec 2020 16:46:08
User entered '07 Dec 2020 10:46:02'	System	07 Dec 2020 16:46:08

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2020-12-11T12:21:40', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd6742fd9-4e7c-48f4-b85f-c287bb2879be'	System	11 Dec 2020 18:22:05
User entered 'No (N)'	System	11 Dec 2020 18:22:05

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2020-12-11T12:21:52', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd6742fd9-4e7c-48f4-b85f-c287bb2879be'	System	11 Dec 2020 18:22:05
User entered 'No (N)'	System	11 Dec 2020 18:22:05

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-12-11T12:21:57', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd6742fd9-4e7c-48f4-b85f-c287bb2879be'	System	11 Dec 2020 18:22:05
User entered '11 Dec 2020 12:21:57'	System	11 Dec 2020 18:22:05

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2020-12-17T12:03:02', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '1380ed79-452e-431d-ade5-a8021c9471eb'	System	17 Dec 2020 18:04:28
User entered 'Yes (Y)'	System	17 Dec 2020 18:04:28

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2020-12-17T12:03:32', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '1380ed79-452e-431d-ade5-a8021c9471eb'	System	17 Dec 2020 18:04:28
User entered 'No (N)'	System	17 Dec 2020 18:04:28

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2020-12-17T12:03:45', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '1380ed79-452e-431d-ade5-a8021c9471eb'	System	17 Dec 2020 18:04:28
User entered 'No (N)'	System	17 Dec 2020 18:04:28

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2020-12-17T12:04:04', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '1380ed79-452e-431d-ade5-a8021c9471eb'	System	17 Dec 2020 18:04:28
User entered 'No (N)'	System	17 Dec 2020 18:04:28

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-12-17T12:04:23', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '1380ed79-452e-431d-ade5-a8021c9471eb' User entered '17 Dec 2020 12:04:23'	System	17 Dec 2020 18:04:28
	System	17 Dec 2020 18:04:28

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2020-12-28T06:41:28', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '89a7a383-a3fe-4e34-8525-6222eb8a857a'	System	28 Dec 2020 12:41:41
User entered 'No (N)'	System	28 Dec 2020 12:41:41

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2020-12-28T06:41:33', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '89a7a383-a3fe-4e34-8525-6222eb8a857a'	System	28 Dec 2020 12:41:41
User entered 'No (N)'	System	28 Dec 2020 12:41:41

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-12-28T06:41:37', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '89a7a383-a3fe-4e34-8525-6222eb8a857a'	System	28 Dec 2020 12:41:41
User entered '28 Dec 2020 06:41:37'	System	28 Dec 2020 12:41:41

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2020-12-31T07:19:01', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'f84a3794-2352-46bc-b80a-9d6f9261f8dd'	System	31 Dec 2020 13:19:15
User entered 'No (N)'	System	31 Dec 2020 13:19:15

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2020-12-31T07:19:06', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'f84a3794-2352-46bc-b80a-9d6f9261f8dd'	System	31 Dec 2020 13:19:15
User entered 'No (N)'	System	31 Dec 2020 13:19:15

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-12-31T07:19:10', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'f84a3794-2352-46bc-b80a-9d6f9261f8dd'	System	31 Dec 2020 13:19:15
User entered '31 Dec 2020 07:19:10'	System	31 Dec 2020 13:19:15

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2021-01-07T06:07:21', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'f4769437-94ea-4cd7-b879-cf84a48fb1c8'	System	07 Jan 2021 12:07:40
User entered 'No (N)'	System	07 Jan 2021 12:07:40

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2021-01-07T06:07:30', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'f4769437-94ea-4cd7-b879-cf84a48fb1c8'	System	07 Jan 2021 12:07:40
User entered 'No (N)'	System	07 Jan 2021 12:07:40

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-01-07T06:07:35', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'f4769437-94ea-4cd7-b879-cf84a48fb1c8'	System	07 Jan 2021 12:07:40
User entered '07 Jan 2021 06:07:35'	System	07 Jan 2021 12:07:40

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2021-01-15T06:47:01', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '11ee23c9-f677-44b5-84c9-e49cfa2c5d17'	System	15 Jan 2021 12:47:15
User entered 'No (N)'	System	15 Jan 2021 12:47:15

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2021-01-15T06:47:08', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '11ee23c9-f677-44b5-84c9-e49cfa2c5d17'	System	15 Jan 2021 12:47:15
User entered 'No (N)'	System	15 Jan 2021 12:47:15

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-01-15T06:47:12', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '11ee23c9-f677-44b5-84c9-e49cfa2c5d17' User entered '15 Jan 2021 06:47:12'	System	15 Jan 2021 12:47:15
	System	15 Jan 2021 12:47:15

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2021-01-25T09:39:23', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '2b093454-87ce-4a8c-8436-54e935cf3361'	System	25 Jan 2021 15:39:40
User entered 'No (N)'	System	25 Jan 2021 15:39:40

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2021-01-25T09:39:31', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '2b093454-87ce-4a8c-8436-54e935cf3361'	System	25 Jan 2021 15:39:40
User entered 'No (N)'	System	25 Jan 2021 15:39:40

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-01-25T09:39:35', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '2b093454-87ce-4a8c-8436-54e935cf3361'	System	25 Jan 2021 15:39:40
User entered '25 Jan 2021 09:39:35'	System	25 Jan 2021 15:39:40

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2021-01-28T14:23:37', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '72e9b180-0b4d-400b-bccd-a40fe7067be4'	System	28 Jan 2021 20:23:51
User entered 'No (N)'	System	28 Jan 2021 20:23:51

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2021-01-28T14:23:41', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '72e9b180-0b4d-400b-bccd-a40fe7067be4'	System	28 Jan 2021 20:23:51
User entered 'No (N)'	System	28 Jan 2021 20:23:51

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-01-28T14:23:45', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '72e9b180-0b4d-400b-bccd-a40fe7067be4'	System	28 Jan 2021 20:23:51
User entered '28 Jan 2021 14:23:45'	System	28 Jan 2021 20:23:51

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2021-02-04T14:27:02', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '8e17ab67-17b2-4e12-a1be-67df6dea90cf'	System	04 Feb 2021 20:27:13
User entered 'No (N)'	System	04 Feb 2021 20:27:13

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2021-02-04T14:27:06', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '8e17ab67-17b2-4e12-a1be-67df6dea90cf'	System	04 Feb 2021 20:27:13
User entered 'No (N)'	System	04 Feb 2021 20:27:13

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-02-04T14:27:09', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '8e17ab67-17b2-4e12-a1be-67df6dea90cf' User entered '04 Feb 2021 14:27:09'	System	04 Feb 2021 20:27:13
	System	04 Feb 2021 20:27:13

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2021-02-11T05:16:09', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '0befd64d-2066-45ae-bd47-4114a65ecbea'	System	11 Feb 2021 11:16:21
User entered 'No (N)'	System	11 Feb 2021 11:16:21

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2021-02-11T05:16:14', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '0befd64d-2066-45ae-bd47-4114a65ecbea'	System	11 Feb 2021 11:16:21
User entered 'No (N)'	System	11 Feb 2021 11:16:21

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-02-11T05:16:18', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '0befd64d-2066-45ae-bd47-4114a65ecbea'	System	11 Feb 2021 11:16:21
User entered '11 Feb 2021 05:16:18'	System	11 Feb 2021 11:16:21

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2021-02-18T14:06:40', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4baaeb5-ed1e-4db9-aae9-9a5b9c915dc5'	System	18 Feb 2021 20:07:06
User entered 'No (N)'	System	18 Feb 2021 20:07:06

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2021-02-18T14:06:52', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4baaeb5-ed1e-4db9-aae9-9a5b9c915dc5'	System	18 Feb 2021 20:07:06
User entered 'No (N)'	System	18 Feb 2021 20:07:06

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-02-18T14:06:55', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4baaeb5-ed1e-4db9-aae9-9a5b9c915dc5'	System	18 Feb 2021 20:07:06
User entered '18 Feb 2021 14:06:55'	System	18 Feb 2021 20:07:06

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2021-02-26T06:08:47-06:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a58019dd-3185-480f-9a1b-76879a523316'	System	26 Feb 2021 12:08:59
User entered 'No (N)'	System	26 Feb 2021 12:08:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2021-02-26T06:07:51-06:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a58019dd-3185-480f-9a1b-76879a523316'	System	26 Feb 2021 12:08:59
User entered 'No (N)'	System	26 Feb 2021 12:08:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-02-26T06:08:56-06:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a58019dd-3185-480f-9a1b-76879a523316'	System	26 Feb 2021 12:08:59
User entered '26 Feb 2021 06:08:56'	System	26 Feb 2021 12:08:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2021-03-04T14:26:21-06:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a2e2e42d-c07d-4ac1-915e-2204309d8239'	System	04 Mar 2021 20:26:49
User entered 'No (N)'	System	04 Mar 2021 20:26:49

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2021-03-04T14:26:36-06:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a2e2e42d-c07d-4ac1-915e-2204309d8239'	System	04 Mar 2021 20:26:49
User entered 'No (N)'	System	04 Mar 2021 20:26:49

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-03-04T14:26:42-06:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a2e2e42d-c07d-4ac1-915e-2204309d8239' User entered '04 Mar 2021 14:26:42'	System	04 Mar 2021 20:26:49
	System	04 Mar 2021 20:26:49

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2021-03-11T14:12:43-06:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5c7c94bd-4d9d-45e1-a4f7-39386831db45'	System	11 Mar 2021 20:13:16
User entered 'No (N)'	System	11 Mar 2021 20:13:16

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2021-03-11T14:12:50-06:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5c7c94bd-4d9d-45e1-a4f7-39386831db45'	System	11 Mar 2021 20:13:16
User entered 'No (N)'	System	11 Mar 2021 20:13:16

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-03-11T14:12:54-06:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5c7c94bd-4d9d-45e1-a4f7-39386831db45'	System	11 Mar 2021 20:13:16
User entered '11 Mar 2021 14:12:54'	System	11 Mar 2021 20:13:16

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2021-03-19T12:24:27-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '80a20008-39b0-4194-855f-f1b1fb7f39a2'	System	19 Mar 2021 17:24:47
User entered 'No (N)'	System	19 Mar 2021 17:24:47

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2021-03-19T12:24:35-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '80a20008-39b0-4194-855f-f1b1fb7f39a2'	System	19 Mar 2021 17:24:47
User entered 'No (N)'	System	19 Mar 2021 17:24:47

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-03-19T12:24:39-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '80a20008-39b0-4194-855f-f1b1fb7f39a2'	System	19 Mar 2021 17:24:47
User entered '19 Mar 2021 12:24:39'	System	19 Mar 2021 17:24:47

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2021-03-25T04:30:17-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd8272024-8321-4eca-9371-9a4b9bb91072'	System	25 Mar 2021 09:30:38
User entered 'No (N)'	System	25 Mar 2021 09:30:38

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2021-03-25T04:30:28-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd8272024-8321-4eca-9371-9a4b9bb91072'	System	25 Mar 2021 09:30:38
User entered 'No (N)'	System	25 Mar 2021 09:30:38

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-03-25T04:30:33-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd8272024-8321-4eca-9371-9a4b9bb91072'	System	25 Mar 2021 09:30:38
User entered '25 Mar 2021 04:30:33'	System	25 Mar 2021 09:30:38

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2021-04-04T11:46:49-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'fcf5d81a-bbb0-44e3-9e11-6314750db706'	System	04 Apr 2021 16:47:09
User entered 'No (N)'	System	04 Apr 2021 16:47:09

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2021-04-04T11:46:57-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'fcf5d81a-bbb0-44e3-9e11-6314750db706'	System	04 Apr 2021 16:47:09
User entered 'No (N)'	System	04 Apr 2021 16:47:09

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-04-04T11:47:00-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'fcf5d81a-bbb0-44e3-9e11-6314750db706'	System	04 Apr 2021 16:47:09
User entered '04 Apr 2021 11:47:00'	System	04 Apr 2021 16:47:09

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2021-04-09T04:52:49-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'e4162d91-b82c-4c04-b738-afe41ff0fc6c' User entered 'No (N)'	System	09 Apr 2021 09:53:05
	System	09 Apr 2021 09:53:05

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2021-04-09T04:52:55-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'e4162d91-b82c-4c04-b738-afe41ff0fc6c'	System	09 Apr 2021 09:53:05
User entered 'No (N)'	System	09 Apr 2021 09:53:05

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-04-09T04:52:59-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'e4162d91-b82c-4c04-b738-afe41ff0fc6c' User entered '09 Apr 2021 04:52:59'	System	09 Apr 2021 09:53:05
	System	09 Apr 2021 09:53:05

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2021-04-16T21:59:35-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a19d75b0-6753-498a-9cae-45afa36218cb' User entered 'No (N)'	System	17 Apr 2021 02:59:53
	System	17 Apr 2021 02:59:53

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2021-04-16T21:59:46-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a19d75b0-6753-498a-9cae-45afa36218cb' User entered 'No (N)'	System	17 Apr 2021 02:59:53

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-04-16T21:59:49-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a19d75b0-6753-498a-9cae-45afa36218cb' User entered '16 Apr 2021 21:59:49'	System	17 Apr 2021 02:59:53
	System	17 Apr 2021 02:59:53

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[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 (db52a8948cfd1968)', Time: '2021-04-26T07:10:22-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'af75b5a6-e030-477c-8fae-1f02b8b75095'	System	26 Apr 2021 12:10:36
User entered 'No (N)'	System	26 Apr 2021 12:10:36

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

Have you been exposed to someone with 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 (db52a8948cfd1968)', Time: '2021-04-26T07:10:28-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'af75b5a6-e030-477c-8fae-1f02b8b75095'	System	26 Apr 2021 12:10:36
User entered 'No (N)'	System	26 Apr 2021 12:10:36

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-04-26T07:10:31-05:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'af75b5a6-e030-477c-8fae-1f02b8b75095'	System	26 Apr 2021 12:10:36
User entered '26 Apr 2021 07:10:31'	System	26 Apr 2021 12:10:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:18:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:18:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:18:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:18:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:18:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 10:18:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 10:18:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:18:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '24 Nov 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Nov 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:43:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:26:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-03-01T04:52:56-06:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'df07e569-56f9-40b6-9848-ccdf635fd0e6'	System	01 Mar 2021 10:53:08
User entered 'No (N)'	System	01 Mar 2021 10:53:08

US3492237

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:43:58

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:26:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2021-03-01T04:53:05-06:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'df07e569-56f9-40b6-9848-ccdf635fd0e6'	System	01 Mar 2021 10:53:08
User entered '01 Mar 2021 04:53:05'	System	01 Mar 2021 10:53:08

US3492237

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:27:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:02:03

US3492237

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:27:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:02:03

US3492237

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:27:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:02:03

US3492237

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:27:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:02:03

US3492237

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:27:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:02:21

US3492237

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:27:08
User entered 'I'	System	15 Dec 2020 17:02:21

US3492237

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	15 Jan 2021 15:48:04

US3492237

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '15 Jan 2021'	Nia Moragne-O'Neal (b) (4)	15 Jan 2021 15:48:04

US3492237

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	15 Jan 2021 15:48:04

US3492237

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	Nia Moragne-O'Neal (b) (4)	15 Jan 2021 15:48:04

US3492237

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	15 Jan 2021 15:48:07

US3492237

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User entered '1'	System	15 Jan 2021 15:48:07

US3492237

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered 'Yes (Y)'	Ian Feather (b) (4)	17 Feb 2021 16:49:26

US3492237

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered '17 Feb 2021'	Ian Feather (b) (4)	17 Feb 2021 16:49:26

US3492237

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered 'Contact Made (CONTACT MADE)'	Ian Feather (b) (4)	17 Feb 2021 16:49:26

US3492237

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered empty.	Ian Feather (b) (4)	17 Feb 2021 16:49:26

US3492237

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered 'Yes (Y)'	Ian Feather (b) (4)	17 Feb 2021 16:49:30

US3492237

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User entered '1'	System	17 Feb 2021 16:49:30

US3492237

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered 'Yes (Y)'	Ian Feather (b) (4)	16 Mar 2021 15:45:41

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Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered '16 Mar 2021'	Ian Feather (b) (4)	16 Mar 2021 15:45:41

US3492237

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered 'Contact Made (CONTACT MADE)'	Ian Feather (b) (4)	16 Mar 2021 15:45:41

US3492237

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered empty.	Ian Feather (b) (4)	16 Mar 2021 15:45:41

US3492237

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered 'Yes (Y)'	Ian Feather (b) (4)	16 Mar 2021 15:45:46

US3492237

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:57
User entered 'I'	System	16 Mar 2021 15:45:46

US3492237

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'Yes (Y)'	Lorna Sanchez McCann	12 Apr 2021 20:15:46
	(b) (4)	

US3492237

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '12 Apr 2021'	Lorna Sanchez McCann	12 Apr 2021 20:15:46
	(b) (4)	

US3492237

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'Clinic (Clinic)'	Lorna Sanchez McCann	12 Apr 2021 20:15:46
	(b) (4)	

US3492237

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	12 Apr 2021 20:15:46

US3492237

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	12 Apr 2021 20:17:35

US3492237

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '12 Apr 2021'	Lorna Sanchez McCann	12 Apr 2021 20:17:35
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '15:04'	Lorna Sanchez McCann	12 Apr 2021 20:17:35
	(b) (4)	

US3492237

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 15:04'	System	12 Apr 2021 20:17:35

US3492237

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '97.3' F	Lorna Sanchez McCann	12 Apr 2021 20:17:35
	(b) (4)	

US3492237

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'Other (Other)'	Lorna Sanchez McCann	12 Apr 2021 20:17:35
	(b) (4)	

US3492237

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'TYMPANIC'	Lorna Sanchez McCann	12 Apr 2021 20:17:35
	(b) (4)	

US3492237

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '79'	Lorna Sanchez McCann	12 Apr 2021 20:17:35
	(b) (4)	

US3492237

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 20:17:35

US3492237

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '16'	Lorna Sanchez McCann	12 Apr 2021 20:17:35
	(b) (4)	

US3492237

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 20:17:35

US3492237

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '102'	Lorna Sanchez McCann	12 Apr 2021 20:17:35
	(b) (4)	

US3492237

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 20:17:35

US3492237

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '69'	Lorna Sanchez McCann	12 Apr 2021 20:17:35
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 20:17:35

US3492237

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'Yes (Y)'	Lorna Sanchez McCann	12 Apr 2021 20:15:55
	(b) (4)	

US3492237

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User entered '12 Apr 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	12 Apr 2021 20:15:55

US3492237

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'Yes (Y)'	Lorna Sanchez McCann	12 Apr 2021 20:22:44
	(b) (4)	

US3492237

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User entered '12 Apr 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	12 Apr 2021 20:22:44

US3492237

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '15:13'	Lorna Sanchez McCann	12 Apr 2021 20:22:44
	(b) (4)	

US3492237

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 15:13'	System	12 Apr 2021 20:22:44

US3492237

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	12 Apr 2021 20:16:01

US3492237

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 20:16:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:58

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:05
User entered '27 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	30 Sep 2020 15:30:17
User entered '28 Sep 2020'	Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:03:04

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:58

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:05
User entered '12:00' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	30 Sep 2020 15:30:17
User entered '11:13'	Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:03:04

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Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:58

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:33
User entered '27 Sep 2020 12:00'	System	30 Sep 2020 15:30:17
User entered '28 Sep 2020 11:13'	System	28 Sep 2020 19:03:04

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:58

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:05
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	30 Sep 2020 15:30:17
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Diana Bahena (b) (4)	28 Sep 2020 19:03:04

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:58

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:05
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:03:04

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Day 1 (Day 1)'	(b) (4) Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:04:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '24 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:15:48
User entered '28 Sep 2020'	Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '1' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:15:48
User entered '0'	(b) (4) Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered '98'	(b) (4) Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User entered empty.	System	01 Oct 2020 21:17:00
User entered '%'	System	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered '100.5' F	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	(b) (4) Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	(b) (4) Diana Bahena (b) (4)	28 Sep 2020 19:04:29
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'Mild (Mild)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	(b) (4) Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:04:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Day 2 (Day 2)'	(b) (4) Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '25 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'I'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User entered empty.	System	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:09

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Day 3 (Day 3)'	(b) (4) Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '26 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'l'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User entered empty.	System	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:19:28

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Day 4 (Day 4)'	(b) (4) Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '27 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'l'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User entered empty.	System	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:20:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Day 5 (Day 5)'	(b) (4) Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '28 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '98'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User entered '%'	System	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '100.5' F	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Day 6 (Day 6)'	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '29 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '96'	Andrea Wendrow (b) (4) (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User entered '%'	System	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '100.0' F	Andrea Wendrow (b) (4) (b) (4)	02 Oct 2020 21:53:38

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Day 8 (Day 8)'	(b) (4) Diana Bahena (b) (4)	05 Oct 2020 21:11:58
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '01 Oct 2020'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '0'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '95'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User entered '%'	System	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '97.5' F	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	05 Oct 2020 21:12:08
User entered empty.	(b) (4) Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Day 9 (Day 9)'	(b) (4) Diana Bahena (b) (4)	05 Oct 2020 21:14:24
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '02 Oct 2020' reason for change: Data Entry Error	Diana Bahena (b) (4)	05 Oct 2020 21:24:53
User entered '02 Sep 2020'	(b) (4) Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '0'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '98'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User entered '%'	System	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '99' F	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Day 12 (Day 12)'	(b) (4) Diana Bahena (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '05 Oct 2020'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '0'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '98'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User entered '%'	System	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '98' F	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Day 7 (Day 7)'	Diana Bahena (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '30 Sep 2020'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'I'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User entered empty.	System	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Day 10 (Day 10)'	Diana Bahena (b) (4)	05 Oct 2020 21:25:56

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '03 Oct 2020'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'l'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User entered empty.	System	05 Oct 2020 21:25:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Day 11 (Day 11)'	Diana Bahena (b) (4)	05 Oct 2020 21:26:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '04 Oct 2020'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'l'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User entered empty.	System	05 Oct 2020 21:26:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Day 13 (Day 13)'	(b) (4) Diana Bahena (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '06 Oct 2020'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '0'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered missing code ND - Not Done.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User entered '%'	System	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered missing code ND - Not Done.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Not Done (Not Done)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Day 14 (Day 14)' reason for change:	(b) (4)	
Data Entry Error	Diana Bahena (b) (4)	12 Oct 2020 20:03:25
User entered empty.	(b) (4)	
	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 20:03:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 20:03:25
User entered '07 Oct 2020' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:25
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 20:03:01
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '1' reason for change: Data Entry Error	Diana Bahena (b) (4)	12 Oct 2020 20:03:25
User entered '0'	(b) (4) Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User entered empty.	System	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Day 15 (Day 15)'	(b) (4) Diana Bahena (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '08 Oct 2020'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '0'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '98'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User entered '%'	System	12 Oct 2020 20:05:02

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '98.2' F	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Day 16 (Day 16)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User closed query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 26OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 11:40:08
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 26OCT2020. Please reconcile or clarify.' answered with 'no this is correct' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	11 Nov 2020 03:57:43
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 26OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:43:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '09 Oct 2020'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '0'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '99'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User entered '%'	System	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '97.5' F	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:58

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:20
User entered '28 Sep 2020'	Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:08:41

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:58

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:20
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:08:41

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:58

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:20
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 12:15:03
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'confirmed' (Site from System).	Andrea Wendrow (b) (4)	01 Oct 2020 20:09:26
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	01 Oct 2020 20:09:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 20:09:12
User entered 'No (N)'	Diana Bahena (b) (4)	28 Sep 2020 19:08:41

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Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:58

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:10
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:57:27
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "22-SEP-2020" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "28-SEP-2020" for Covid-19 Assessment visit. Kindly review the collection date and update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 09:55:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "22-SEP-2020" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "28-SEP-2020" for Covid-19 Assessment visit. Kindly review the collection date and update as appropriate, else clarify. ' answered with 'updated' (Site from DM).	(b) (4) Diana Bahena (b) (4)	03 Feb 2021 20:26:01
DataPoint Un-verified.	(b) (4) Diana Bahena (b) (4)	03 Feb 2021 20:25:55
User entered '28 Sep 2020' reason for change: Data Entry Error	(b) (4) Diana Bahena (b) (4)	03 Feb 2021 20:25:55
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "22-SEP-2020" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "28-SEP-2020" for Covid-19 Assessment visit. Kindly review the collection date and update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 08:13:03
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:20
User entered '22 Sep 2020'	Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:08:41

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Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:58

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:20
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:08:41

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:58

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:20
User entered empty.	Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:08:41

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:58

[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)	03 May 2021 03:40:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:20
User entered 'No (N)'	Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:08:41

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:58

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:20
User entered empty.	Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:08:41

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:58

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:20
User entered empty.	Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:08:41

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:58

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:10
User entered '1'	System	01 Oct 2020 20:09:12
User entered '0'	System	28 Sep 2020 19:08:41

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:58

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:58

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:58

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

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Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
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Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

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[Start Date](#)

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

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[PaO2](#)

Audit	User	Time (GMT)
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

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[High-Flow Oxygen?](#)

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User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
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Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

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User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

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User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly as it appears to be missing some responses.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 16:17:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly as it appears to be missing some responses.' answered with '-----Updated. Thank you.-----' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 20:43:59
User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly as it appears to be missing some responses.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 22:43:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
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[Evidence of Shock Requires
Vasopressors](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:57:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:43:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
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DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:43:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 20:43:23
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[Hepatic Dysfunction?](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:57:32
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[Neurologic Dysfunction?](#)

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DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:43:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 20:43:23
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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:58

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:58

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:58

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:57:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:43:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:58

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:58

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:58

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:58

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:14:56

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:43:58

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:39:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:35
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:53:05
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:08:52

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:43:58

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:43:58

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:11
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:43:58

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:11
User entered '30 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:43:58

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:43:58

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:11
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 21:52:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 21:52:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	02 Oct 2020 21:52:25
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:12:26
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:43:58

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02OCT2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 06:24:18
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02OCT2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with "Day 5 is 1F602728610, Day 9 is 1F616907338, Day 14 is 1F604318818, Day 21 is 1F604256802. All samples are on site as there has been an issue logging in that has been reported by our lab and Preclarus has yet to resolve ' (Site from DM)' (Site from DM).	Andrea Wendrow (b) (4)	12 Apr 2021 20:26:18
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02OCT2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:58:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02,06,11,18OCT2020 is recorded under Illness Visit Day 5,9,14,21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:02:33

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EAB) (1725)

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:43:58

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02,06,11,18OCT2020 is recorded under Illness Visit Day 5,9,14,21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Day 5 is 1F602728610, Day 9 is 1F616907338, Day 14 is 1F604318818, Day 21 is 1F604256802. All samples are on site as there has been an issue logging in that has been reported by our lab and Preclarus has yet to resolve ' (Site from DM).	Andrea Wendrow (b) (4)	(b) (4) 04 Dec 2020 21:24:18
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02,06,11,18OCT2020 is recorded under Illness Visit Day 5,9,14,21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 07:57:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User entered '2 Oct 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	(b) (4) 02 Oct 2020 21:52:25
User entered empty.	Andrea Wendrow (b) (4)	(b) (4) 01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:43:58

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:43:58

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:11
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 23:33:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 23:33:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 23:33:34
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:12:26
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:43:58

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:11
User entered '4 Oct 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	09 Oct 2020 23:33:34
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:43:58

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:43:58

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:11
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 23:33:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 23:33:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 23:33:34
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:12:26
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:43:58

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is recorded under Illness Visit Day 9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 06:24:25
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is recorded under Illness Visit Day 9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with "Day 5 is 1F602728610, Day 9 is 1F616907338, Day 14 is 1F604318818, Day 21 is 1F604256802. All samples are on site as there has been an issue logging in that has been reported by our lab and Preclarus has yet to resolve ' (Site from DM)' (Site from DM).	Andrea Wendrow (b) (4)	12 Apr 2021 20:27:31
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is recorded under Illness Visit Day 9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:59:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User entered '6 Oct 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	09 Oct 2020 23:33:34
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:43:58

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:43:58

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:11
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 14:45:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 14:45:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 14:45:46
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:12:26
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:43:58

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11OCT2020 is recorded under Illness Visit Day 14 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. '(Site from DM).	(b) (4), (b) (6)	16 Apr 2021 06:24:30
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11OCT2020 is recorded under Illness Visit Day 14 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with "Day 5 is 1F602728610, Day 9 is 1F616907338, Day 14 is 1F604318818, Day 21 is 1F604256802. All samples are on site as there has been an issue logging in that has been reported by our lab and Preclarus has yet to resolve ' (Site from DM).	Andrea Wendrow (b) (4)	12 Apr 2021 20:28:46
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11OCT2020 is recorded under Illness Visit Day 14 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. '(Site from DM).	(b) (4), (b) (6)	23 Mar 2021 10:00:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User entered '11 Oct 2020' reason for change: Data Entry Error	Diana Bahena (b) (4)	20 Oct 2020 14:45:46
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:43:58

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:43:58

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:11
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 14:45:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 14:45:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 14:45:46
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:12:26
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:43:58

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18OCT2020 is recorded under Illness Visit Day 21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 06:24:40
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18OCT2020 is recorded under Illness Visit Day 21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Day 5 is 1F602728610, Day 9 is 1F616907338, Day 14 is 1F604318818, Day 21 is 1F604256802. All samples are on site as there has been an issue logging in that has been reported by our lab and Preclarus has yet to resolve' (Site from DM).	Andrea Wendrow (b) (4)	12 Apr 2021 20:29:34
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18OCT2020 is recorded under Illness Visit Day 21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 10:00:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User entered '18 Oct 2020' reason for change: Data Entry Error	Diana Bahena (b) (4)	20 Oct 2020 14:45:46
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:43:58

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:43:58

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:11
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 20:57:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 20:57:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 20:57:09
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:12:26
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:43:58

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:11
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Oct 2020 20:57:20
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 20:57:20
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Oct 2020 20:57:09
User entered '26 Oct ' (non-conformant).	(b) (4), (b) (6)	26 Oct 2020 20:57:09
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:48
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:36:45

US3492237

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:48
User entered '28 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:36:45

US3492237

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:48
User entered 'Home (Home)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:36:45

US3492237

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User entered 'SICKD1'	System	01 Oct 2020 20:36:45

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered '28 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered '11:13'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User entered '28 Sep 2020 11:13'	System	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered missing code ND - Not Done.	Andrea Wendrow (b) (4)	01 Oct 2020 21:09:25
DataPoint set to visible.	(b) (4) System	01 Oct 2020 20:36:45

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered missing code ND - Not Done.	Andrea Wendrow (b) (4)	01 Oct 2020 21:09:25
DataPoint set to visible.	(b) (4) System	01 Oct 2020 20:36:45

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered '100.5' F	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered 'Oral (Oral)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered '97'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User entered 'bpm'	System	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered '20'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User entered 'breaths/min'	System	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered '118'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User entered 'mmHg'	System	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered '68'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User entered 'mmHg'	System	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40

US3492237

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:10
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:09:51

US3492237

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:10
User entered '28 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:09:51

US3492237

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:43:58

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:16
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:10:07

US3492237

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:43:58

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:16
User entered '28 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:10:07

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 20:53:30

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:24
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 20:53:30

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:24
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Oct 2020 20:53:30

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User entered 'SICKD28'	System	26 Oct 2020 20:53:30

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered '15:10'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User entered '26 Oct 2020 15:10'	System	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:32
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 20:56:18
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Oct 2020 20:56:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 20:56:18
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 20:54:35
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 20:54:35
DataPoint set to visible.	System	26 Oct 2020 20:53:30

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:32
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 20:56:18
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Oct 2020 20:56:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 20:56:18
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 20:54:35
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 20:54:35
DataPoint set to visible.	System	26 Oct 2020 20:53:30

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered '97.6' F	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered 'Other (Other)'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered 'Tympanic'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered '73'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User entered 'bpm'	System	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered '20'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User entered 'breaths/min'	System	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered '135'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User entered 'mmHg'	System	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered '85'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User entered 'mmHg'	System	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:02:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 20:56:28

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:02:50
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 20:56:28

US3492237

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:43:58

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 20:56:38

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Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:43:58

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:42
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 20:56:38

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

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	28 Jan 2021 21:26:37
	(b) (4)	

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

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '28 Jan 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:26:37

US3492237

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

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Clinic (Clinic)'	(b) (4) Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:26:37

US3492237

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

Form: Visit Date

Generated On: 11 Aug 2021 22:43:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 21:26:37

US3492237

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:58

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '28 Jan 2021'	(b) (4) Lorna Sanchez McCann	28 Jan 2021 21:26:52
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:58

[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 20:27:36
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:52:02

US3492237

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:58

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:26:52

US3492237

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:58

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:52:02

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:58

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '28 Jan 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:26:52

US3492237

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:58

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'mRNA-1273 (mRNA-1273)'	Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:26:52

US3492237

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:58

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:26:52

US3492237

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:58

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Not Administered (NA)'	Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:26:52

US3492237

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:58

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:26:52

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:58

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered empty.	System	28 Jan 2021 21:26:52

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:58

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered 'I'	System	28 Jan 2021 21:26:52

US3492237

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann	28 Jan 2021 21:27:45
	(b) (4)	

US3492237

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann	28 Jan 2021 21:27:45
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered empty.	System	28 Jan 2021 21:27:45
DataPoint set to visible.	System	28 Jan 2021 21:26:52

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann	28 Jan 2021 21:27:45
	(b) (4)	

US3492237

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann	28 Jan 2021 21:27:45
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered empty.	System	28 Jan 2021 21:27:45
DataPoint set to visible.	System	28 Jan 2021 21:26:52

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User accepted default value 'Pre-Dose (PREDOSE)'	Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:27:45

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	28 Jan 2021 21:27:45
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '28 Jan 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:27:45

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '14:55'	(b) (4) Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:27:45

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered '28 Jan 2021 14:55'	System	28 Jan 2021 21:27:45

US3492237

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '98.1' F	Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:27:45

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Other (Other)'	Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:27:45

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'tympanic'	(b) (4) Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:27:45

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '79'	Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:27:45

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered 'bpm'	System	28 Jan 2021 21:27:45

US3492237

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '18'	Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:27:45

US3492237

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered 'breaths/min'	System	28 Jan 2021 21:27:45

US3492237

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '148'	(b) (4) Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:27:45

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered 'mmHg'	System	28 Jan 2021 21:27:45

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '75'	(b) (4) Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:27:45

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered 'mmHg'	System	28 Jan 2021 21:27:45

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann	28 Jan 2021 21:27:45
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann	28 Jan 2021 21:27:45
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered empty.	System	28 Jan 2021 21:27:45
DataPoint set to visible.	System	28 Jan 2021 21:26:52

US3492237

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User accepted default value 'Post-Dose (POSTDOSE)'	Michelle Agnoli (b) (4) (b) (4)	28 Jan 2021 22:00:28

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) Michelle Agnoli (b) (4) (b) (4)	28 Jan 2021 22:00:28

US3492237

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '28 Jan 2021'	(b) (4) Michelle Agnoli (b) (4)	28 Jan 2021 22:00:28

US3492237

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '15:54'	Michelle Agnoli (b) (4)	28 Jan 2021 22:00:28

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered '28 Jan 2021 15:54'	System	28 Jan 2021 22:00:28

US3492237

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '98.1' F	Michelle Agnoli (b) (4)	28 Jan 2021 22:00:28

US3492237

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	(b) (4) System	28 Jan 2021 22:13:00
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Jan 2021 22:01:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).		28 Jan 2021 22:01:42
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	28 Jan 2021 22:01:42
User entered 'Other (Other)' reason for change: Per Query Resolution	Michelle Agnoli (b) (4) (b) (4)	28 Jan 2021 22:01:42
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Jan 2021 22:00:28
User entered empty.	Michelle Agnoli (b) (4) (b) (4)	28 Jan 2021 22:00:28

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'TYMPANIC' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	28 Jan 2021 22:13:30
User entered 'typmanic' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	28 Jan 2021 22:13:00
User entered empty.	Michelle Agnoli (b) (4)	28 Jan 2021 22:00:28

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Jan 2021 22:01:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	28 Jan 2021 22:01:42
User entered '77' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	28 Jan 2021 22:01:42
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Jan 2021 22:00:28
User entered empty.	System	28 Jan 2021 22:00:28
	Michelle Agnoli (b) (4)	28 Jan 2021 22:00:28
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered 'bpm'	System	28 Jan 2021 22:01:42
User entered empty.	System	28 Jan 2021 22:00:28

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Jan 2021 22:01:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	28 Jan 2021 22:01:42
User entered '16' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	28 Jan 2021 22:01:42
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Jan 2021 22:00:28
User entered empty.	System	28 Jan 2021 22:00:28
	Michelle Agnoli (b) (4)	28 Jan 2021 22:00:28
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered 'breaths/min'	System	28 Jan 2021 22:01:42
User entered empty.	System	28 Jan 2021 22:00:28

US3492237

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Jan 2021 22:01:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	28 Jan 2021 22:01:42
User entered '132' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	28 Jan 2021 22:01:42
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Jan 2021 22:00:28
User entered empty.	Michelle Agnoli (b) (4)	28 Jan 2021 22:00:28
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered 'mmHg'	System	28 Jan 2021 22:01:42
User entered empty.	System	28 Jan 2021 22:00:28

US3492237

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Jan 2021 22:01:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	28 Jan 2021 22:01:42
User entered '75' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	28 Jan 2021 22:01:42
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Jan 2021 22:00:28
User entered empty.	System	28 Jan 2021 22:00:28
	Michelle Agnoli (b) (4)	28 Jan 2021 22:00:28
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered 'mmHg'	System	28 Jan 2021 22:01:42
User entered empty.	System	28 Jan 2021 22:00:28

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	28 Jan 2021 21:27:50
	(b) (4)	

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '28 Jan 2021'	Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:27:50

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	03 Mar 2021 17:34:48

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered empty.	Andrea Wendrow (b) (4)	03 Mar 2021 17:34:48

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered empty.	Andrea Wendrow (b) (4)	03 Mar 2021 17:34:48

US3492237

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered 'mRNA-1273'	System	03 Mar 2021 17:34:48
DataPoint set to visible.	System	28 Jan 2021 21:26:52

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered '28 Jan 2021'	(b) (4) Andrea Wendrow (b) (4)	03 Mar 2021 17:34:48

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered '15:50'	(b) (4) Andrea Wendrow (b) (4)	03 Mar 2021 17:34:48

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered '28 Jan 2021 15:50'	System	03 Mar 2021 17:34:48

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:55
User entered 'Left Arm (LEFT ARM)'	Andrea Wendrow (b) (4)	03 Mar 2021 17:34:48

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered 'ONCE'	System	03 Mar 2021 17:34:48

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered 'INTRAMUSCULAR'	System	03 Mar 2021 17:34:48

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:28:04

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '28 Jan 2021'	(b) (4) Lorna Sanchez McCann	28 Jan 2021 21:28:04
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '14:37'	(b) (4) Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:28:04

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered '28 Jan 2021 14:37'	System	28 Jan 2021 21:28:04

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:43:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	28 Jan 2021 21:28:14
	(b) (4)	

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:43:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '28 Jan 2021'	Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:28:14

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:43:58

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '14:45'	(b) (4) Lorna Sanchez McCann (b) (4)	28 Jan 2021 21:28:14

US3492237

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:43:58

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered '28 Jan 2021 14:45'	System	28 Jan 2021 21:28:14

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

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	28 Jan 2021 21:28:18
	(b) (4)	

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

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered 'I'	System	28 Jan 2021 21:28:18

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:54:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:08:37

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:54:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:08:37

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:54:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:08:37

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:54:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:08:37

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:54:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:08:54

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:54:13
User entered 'I'	System	04 Feb 2021 19:08:54

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:58

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:54:13
User entered '1'	System	04 Feb 2021 19:08:54
DataPoint set to visible.	System	04 Feb 2021 19:08:54

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:43:58

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:27
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 3; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 14:47:19
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 18). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 14:47:17
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of CHILLS persist beyond Day 7 (start date: Day 3; end date: Day 13). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 14:47:15
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 3; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated' (Site from DM).	Diana Bahena (b) (4) (b) (4)	09 Apr 2021 20:32:53
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 18). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated' (Site from DM).	Diana Bahena (b) (4) (b) (4)	09 Apr 2021 20:32:25

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:43:58

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of CHILLS persist beyond Day 7 (start date: Day 3; end date: Day 13). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated ' (Site from DM).	Diana Bahena (b) (4)	09 Apr 2021 20:32:01
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 3; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:09:54
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 18). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:09:47
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of CHILLS persist beyond Day 7 (start date: Day 3; end date: Day 13). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:09:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:01
User entered 'Yes (Y)'	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:15:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	09 Apr 2021 20:40:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Apr 2021 20:40:51
	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 20:39:37
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
Data point term sent to Coder	System	03 Oct 2020 19:03:14
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 21:27:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 21:27:51
	(b) (4)	
Data point term sent to Coder	System	28 Sep 2020 21:27:02
User entered 'headache'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered 'No (N)'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	28 Sep 2020 22:55:54
	(b) (4)	
User entered 'No (N)'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User closed query 'PV Query Urgent: As an event of Covid-19 has already been reported, and this is only a symptom of Covid-19 and not the actual infection, please change answer to No.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:30:13
Query 'PV Query Urgent: As an event of Covid-19 has already been reported, and this is only a symptom of Covid-19 and not the actual infection, please change answer to No.' answered with 'updated' (Site from Safety).	Diana Bahena (b) (4)	09 Apr 2021 20:48:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Apr 2021 20:48:16
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
User opened query 'PV Query Urgent: As an event of Covid-19 has already been reported, and this is only a symptom of Covid-19 and not the actual infection, please change answer to No.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 22:28:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:54:48
User entered 'No (N)'	Richard Novak (b) (4)	28 Sep 2020 21:26:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered '24 Sep 2020'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered empty.	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered empty.	System	28 Sep 2020 21:26:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Diana Bahena (b) (4)	09 Apr 2021 20:48:16
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered 'Yes (Y)'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
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	09 Apr 2021 20:48:52
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	09 Apr 2021 20:48:52
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	09 Apr 2021 20:48:16
User entered '30 Sep 2020' reason for change: Data Entry Error	Diana Bahena (b) (4)	09 Apr 2021 20:48:16
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered empty.	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered empty.	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered empty.	System	28 Sep 2020 21:26:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered 'No (N)'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered '0'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered '0'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered '0'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered empty.	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered empty.	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered empty.	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered empty.	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered '0'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered '0'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered '0'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered 'None (NONE)'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered '0'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered 'I'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered '0'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Diana Bahena (b) (4)	09 Apr 2021 20:48:52
Data Entry Error	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered empty.	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered 'Participant called to report 4 days of headache and dizziness, took ibuprofen and Exedrin with some relief but the symptoms recurred. Headache is different than her usual migraines.'	Richard Novak (b) (4)	28 Sep 2020 21:26:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered '0'	System	28 Sep 2020 21:26:04

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	
User entered '0'	System	28 Sep 2020 21:26:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:22
DataPoint activated with code reason code Data required.	Diana Bahena (b) (4)	09 Apr 2021 20:39:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	03 Oct 2020 19:02:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:07:28
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:07
User entered	System	02 Oct 2020 12:21:58
'USA-US101-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	02 Oct 2020 12:21:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User closed query 'Per MM, Action taken with IP is "none". Please confirm that study drug was discontinued per protocol 7.2.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:43:24
Query 'Per MM, Action taken with IP is "none". Please confirm that study drug was discontinued per protocol 7.2.' answered with 'confirmed' (Site from DM).	Andrea Wendrow (b) (4)	05 Nov 2020 21:12:14
User opened query 'Per MM, Action taken with IP is "none". Please confirm that study drug was discontinued per protocol 7.2.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 10:28:19
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 20:27:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	01 Oct 2020 20:27:49
Data point term sent to Coder	System	01 Oct 2020 20:26:12
User entered 'covid-19 infection'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:56:15
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:31:13
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:30:58
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:49:36
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '22 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '14:00'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 14:00'	System	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered 'No (N)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:34:42
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 23:59:27
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 'done' (Site from Safety).	Andrea Wendrow (b) (4)	01 Nov 2020 21:34:56
	(b) (4)	
User entered '9 Oct 2020' reason for change: New Information	Andrea Wendrow (b) (4)	01 Nov 2020 21:34:42
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:52:56
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 15:56:26
Query 'Data is required. Please provide.' answered with 'not required' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:35:11
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Nov 2020 21:34:42
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

US3492237

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 23:59:37
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 15:56:39
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'is SAE-Covid 19 infection' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:35:37
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'corrected' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:35:25
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	01 Nov 2020 21:34:42
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:34:42
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:54:35
User entered 'None (NONE)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Nov 2020 03:14:42
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Nov 2020 03:12:52
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User closed query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and reconcile AE term and CM indication, so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 11:41:06
Query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and reconcile AE term and CM indication, so there will be an appropriate match. Update eCRF as appropriate.' answered with 'took tylenol for fever, naproxen for mylagias and body aches associated with COVID infection' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	18 Nov 2020 23:07:25
User opened query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and reconcile AE term and CM indication, so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 03:08:53
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:18:56
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'CM taken for symptoms of this AE, as recorded in CM log.' (Site from DM).	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 17:31:14
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:58:53
User closed query 'Per CDM re-query: Previous response states 'corrected', however the medication still has the same indication recorded. Please review and update or clarify what was updated.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:44:20
Query 'Per CDM re-query: Previous response states 'corrected', however the medication still has the same indication recorded. Please review and update or clarify what was updated.' answered with 'changed to fever' (Site from DM).	Andrea Wendrow (b) (4)	06 Nov 2020 03:17:39
User entered '1' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	06 Nov 2020 03:14:42
User entered '0' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	06 Nov 2020 03:12:52
User opened query 'Per CDM re-query: Previous response states 'corrected', however the medication still has the same indication recorded. Please review and update or clarify what was updated.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:04:28
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is "TREAT FEVER". Please review and reconcile AE term and CM indication, so there will be an appropriate match. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:04:28
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is "TREAT FEVER". Please review and reconcile AE term and CM indication, so there will be an appropriate match. Review and update eCRF as appropriate.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	01 Nov 2020 21:35:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is "TREAT FEVER". Please review and reconcile AE term and CM indication, so there will be an appropriate match. Review and update eCRF as appropriate.' (Site from DM). User entered '1'	(b) (4), (b) (6) (b) (4) Andrea Wendrow (b) (4)	30 Oct 2020 07:48:53 01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 23:59:49
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:35:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:34:42
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:53:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Form: Adverse Events (3)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User closed query 'Per DM CLR: SAE Narrative = WAS FINE UNTIL 9/24 WHEN HE REPORTS CHILLS AND FELT FEVERISH. Please review and confirm if this is the start date of this AE. If yes, please reconcile data with the AE start date as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 11:39:31
Query 'Per DM CLR: SAE Narrative = WAS FINE UNTIL 9/24 WHEN HE REPORTS CHILLS AND FELT FEVERISH. Please review and confirm if this is the start date of this AE. If yes, please reconcile data with the AE start date as appropriate. Otherwise, clarify.' answered with 'COVID positive on 9/22' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	18 Nov 2020 23:01:35
User opened query 'Per DM CLR: SAE Narrative = WAS FINE UNTIL 9/24 WHEN HE REPORTS CHILLS AND FELT FEVERISH. Please review and confirm if this is the start date of this AE. If yes, please reconcile data with the AE start date as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 03:09:17
User closed query 'PV Query: Please provide the start date for the following concomitant medications: Advair, Montelukast, fluticasone and azelastine.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 18:25:21
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 18:25:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
Query 'PV Query: Please provide the start date for the following concomitant medications: Advair, Montelukast, fluticasone and azelastine.' answered with 'subject does not recall start dates but has been taking since prior to start of study' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	06 Nov 2020 03:23:13
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'please clarify what you are asking for? Subject has asthma but not considered moderate by clinician' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	06 Nov 2020 03:22:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the start date for the following concomitant medications: Advair, Montelukast, fluticasone and azelastine.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 20:13:49
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 20:13:35
User closed query 'PV Query: Please provide the start date for the following concomitant medications: Advair, Montelukast, fluticasone and azelastine.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 00:00:27
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 00:00:24
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 00:00:19
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 00:00:15
User closed query 'Per DM CLR: SAE Narrative = PATIENT HAS ASTHMA. However, this is not recorded in the MH eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:04:55
Query 'Per DM CLR: SAE Narrative = PATIENT HAS ASTHMA. However, this is not recorded in the MH eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	(b) (4) 01 Nov 2020 21:48:46
Query 'PV Query: Please provide the start date for the following concomitant medications: Advair, Montelukast, fluticasone and azelastine.' answered with 'corrected' (Site from Safety).	Andrea Wendrow (b) (4)	(b) (4) 01 Nov 2020 21:48:39
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4)	(b) (4) 01 Nov 2020 21:36:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4)	(b) (4) 01 Nov 2020 21:36:15
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4)	(b) (4) 01 Nov 2020 21:36:08
User opened query 'Per DM CLR: SAE Narrative = PATIENT HAS ASTHMA. However, this is not recorded in the MH eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:49:27
User opened query 'PV Query: Please provide the start date for the following concomitant medications: Advair, Montelukast, fluticasone and azelastine.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:54:20
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:54:11
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:54:05
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:53:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT CALLED study staff on 27Sep2020TO REPORT THAT HE HAS BEEN HAVING SYMPTOMS OF A RESPIRATORY INFECTION. HE RECEIVED HIS FIRST DOSE OF IP ON 9/22, WAS FINE UNTIL 9/24 WHEN HE REPORTS CHILLS AND FELT FEVERISH. HIS TEMP THAT DAY WAS ABOUT 99. THE FOLLOWING DAY HE DEVELOPED HEADACHE, CONTINUED WITH FEVER TO 101 AND CHILLS. YESTERDAY 9/26, HE DEVELOPED A PRODUCTIVE COUGH, SCANTY CLEAR SPUTUM. HE HAS BEEN TAKING NAPROSYN DAILY SINCE THE FEVERS BEGAN WITH SOME RELIEF. NO LOCALIZED INJECTION SITE PAIN. NO SOB. HE HAS ASTHMA AND CONTINUES TO USE HIS INHALER. NO KNOWN SICK CONTACTS ALTHOUGH HE REPORTS HIS WIFE IS HAVING A FLARE OF FIBROMYALGIA AND HAS A LOW GRADE FEVER.' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:59:42
User entered 'Participant called to report that he has been having symptoms of a respiratory infection. He received his first dose of IP on 9/22, was fine until 9/24 when he reports chills and felt feverish. His temp that day was about 99. The following day he developed headache, continued with fever to 101 and chills. Yesterday 9/26, he developed a productive cough, scanty clear sputum. He has been taking naprosyn daily since the fevers began with some relief. No localized injection site pain. No SOB. He has asthma and continues to use his inhaler. No known sick contacts although he reports his wife is having a flare of fibromyalgia and has a low grade fever.'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:43:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Apr 2021 20:37:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 20:37:49
Data point term sent to Coder	System	09 Apr 2021 20:36:35
User entered 'Chills'	Diana Bahena (b) (4) (b) (4)	09 Apr 2021 20:35:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'No (N)'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 May 2021 00:36:23
Query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' answered with 'Symptom of COVID 19 infection' (Site from DM). Signature has been broken.	Marla Schwarber (b) (4)	29 Apr 2021 19:04:50
User entered 'No (N)' reason for change: Per Query Resolution	Marla Schwarber (b) (4)	29 Apr 2021 19:03:41
User opened query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 20:51:19
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User entered 'Yes (Y)'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'Yes (Y)'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '24 Sep 2020'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 20:35:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'No (N)'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '06 Oct 2020'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 20:35:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'No (N)'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 20:36:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 20:36:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Diana Bahena (b) (4)	09 Apr 2021 20:36:01
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 20:35:52
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 20:36:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 20:36:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Diana Bahena (b) (4)	09 Apr 2021 20:36:01
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 20:35:52
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 20:36:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 20:36:01
User entered 'None (NONE)' reason for change: Data Entry Error	Diana Bahena (b) (4)	09 Apr 2021 20:36:01
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 20:35:52
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'I'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Diana Bahena (b) (4) (b) (4)	09 Apr 2021 20:35:52

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Folder: Adverse Events

Form: Adverse Events (4)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:35:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 20:35:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:43:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 20:35:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 20:39:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 20:39:46
Data point term sent to Coder	System	09 Apr 2021 20:38:36
User entered 'Fatigue'	Diana Bahena (b) (4)	09 Apr 2021 20:38:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 20:38:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 20:38:10
User entered 'No (N)' reason for change: Data Entry Error	Diana Bahena (b) (4)	09 Apr 2021 20:38:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 20:38:01
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 May 2021 00:36:31
Query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' answered with 'Symptom of COVID 19 infection' (Site from DM). Signature has been broken.	Marla Schwarber (b) (4)	29 Apr 2021 19:05:12
User entered 'No (N)' reason for change: Per Query Resolution	Marla Schwarber (b) (4)	29 Apr 2021 19:05:06
User opened query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 20:51:37
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User entered 'Yes (Y)'	Diana Bahena (b) (4)	09 Apr 2021 20:38:01

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4) (b) (4)	09 Apr 2021 20:38:01

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '22 Sep 2020'	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:47:30
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Diana Bahena (b) (4) (b) (4)	09 Apr 2021 20:38:25
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Apr 2021 20:38:01
User entered empty.	Diana Bahena (b) (4) (b) (4)	09 Apr 2021 20:38:01

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 20:38:01

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'No (N)'	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '10 Oct 2020'	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:47:31
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Diana Bahena (b) (4) (b) (4)	09 Apr 2021 20:38:30
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Apr 2021 20:38:01
User entered empty.	Diana Bahena (b) (4) (b) (4)	09 Apr 2021 20:38:01

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 20:38:01

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Diana Bahena (b) (4) (b) (4)	09 Apr 2021 20:38:01

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'No (N)'	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User entered 'Not Related (NOT RELATED)'	(b) (4) Diana Bahena (b) (4) (b) (4)	09 Apr 2021 20:38:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User entered 'Not Related (NOT RELATED)'	(b) (4) Diana Bahena (b) (4) (b) (4)	09 Apr 2021 20:38:01

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'None (NONE)'	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered 'I'	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Diana Bahena (b) (4) (b) (4)	09 Apr 2021 20:38:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:21
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 20:38:01
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 20:38:01

US3492237

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:43:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 20:38:10

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:43:58

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:27
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:11:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:13:47
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 Sep 2020 21:13:47
Data point term sent to Coder User entered 'advair'	System (b) (4), (b) (6)	22 Sep 2020 21:12:47 22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:08:15
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:45:05
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 01:37:05
User entered 'asthma'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '500-50'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:08:17
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:46:40
User entered 'ug (ug)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:46:29
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 01:37:45
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'I'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 21:17:53
	(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 Sep 2020 21:17:53
	(b) (4)	
Data point term sent to Coder	System	22 Sep 2020 21:16:54
User entered 'montelukast'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'asthma'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '10'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'I'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:18:39
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 Sep 2020 21:18:39
Data point term sent to Coder	System	22 Sep 2020 21:17:55
User entered 'fluticasone'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:08:39
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:46:57
' answered with 'corrected' (Site from DM).		
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:11:46
User entered 'allergic rhinitis'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '100'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:14:28
Query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' answered with 'QUERY RESOLVED' (Site from DM).	Gizelle Alvarez (b) (4) (b) (4)	07 Oct 2020 15:12:41
User entered 'ug (ug)' reason for change: Per Query Resolution	Gizelle Alvarez (b) (4) (b) (4)	07 Oct 2020 15:12:29
User opened query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:52:55
User entered 'Other (OTHER)'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty; reason for change Per Query Resolution	Gizelle Alvarez (b) (4) (b) (4)	07 Oct 2020 15:12:29
User entered 'mcg'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'twice daily (BID)'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'I'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS, PRODUCT: AZELASTINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Dec 2020 03:53:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 03:53:45
Data point term sent to Coder	System	10 Dec 2020 00:28:55
DataPoint Un-verified.	Marla Schwarber (b) (4) (b) (4)	10 Dec 2020 00:28:27
Coding entries removed.	Marla Schwarber (b) (4) (b) (4)	10 Dec 2020 00:28:27
User entered 'AZELASTINE (0.1% - 137 mcg/spray)' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	10 Dec 2020 00:28:27
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	06 Nov 2020 17:07:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS, PRODUCT: AZELASTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:19:41
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 Sep 2020 21:19:41
Data point term sent to Coder	System	22 Sep 2020 21:18:59
User entered 'azelastine'	(b) (4), (b) (6) (b) (4)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:08:45
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:47:10
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:46:03
User entered 'allergic rhinitis'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Un-verified.	(b) (4)	
	Marla Schwarber (b) (4)	10 Dec 2020 00:28:27
	(b) (4)	
User entered '548' reason for change: New Information	Marla Schwarber (b) (4)	10 Dec 2020 00:28:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:07:40
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review and remove the units (SPRAY) in the Dose field as this should only be captured in the 'Dose Unit' field. Update as appropriate. ' (Site from DM).		02 Nov 2020 16:08:49
Query 'Per DM CLR: Please review and remove the units (SPRAY) in the Dose field as this should only be captured in the 'Dose Unit' field. Update as appropriate. ' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	01 Nov 2020 21:47:32
	(b) (4)	
User entered '2' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Nov 2020 21:47:24
	(b) (4)	
User opened query 'Per DM CLR: Please review and remove the units (SPRAY) in the Dose field as this should only be captured in the 'Dose Unit' field. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:46:16
User entered '2 spray'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 137 ug, 205.5 ug, etc) instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 07:20:28
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 137 ug, 205.5 ug, etc) instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	10 Dec 2020 00:28:47
DataPoint Un-verified.	Marla Schwarber (b) (4) (b) (4)	10 Dec 2020 00:28:27
User entered 'ug (ug)' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	10 Dec 2020 00:28:27
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 137 ug, 205.5 ug, etc) instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:22:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'puff (PUFF)'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
	(b) (4)	
DataPoint Un-verified.	Marla Schwarber (b) (4)	10 Dec 2020 00:28:27
	(b) (4)	
User entered 'once daily (QD)' reason for change:	Marla Schwarber (b) (4)	10 Dec 2020 00:28:27
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
	(b) (4), (b) (6)	
User entered 'twice daily (BID)'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'I'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 21:18:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 21:18:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 21:18:16
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 21:18:00
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Dec 2020 00:28:27
User entered '2'	System	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
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)	18 Nov 2020 23:10:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 23:10:49
Data point term sent to Coder	System	18 Nov 2020 23:09:43
Coding entries removed.	Andrea Wendrow (b) (4)	18 Nov 2020 23:09:07
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
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)	28 Sep 2020 18:10:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:10:51
Data point term sent to Coder	System	28 Sep 2020 18:09:52
User entered 'TYLENOL'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User closed query 'Per DM CLR: Please confirm if this is used as Prophylaxis. If not, please review and update response if this should be changed. Otherwise, please provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 07:21:04
Query 'Per DM CLR: Please confirm if this is used as Prophylaxis. If not, please review and update response if this should be changed. Otherwise, please provide clarification.' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	09 Dec 2020 21:48:15
DataPoint Un-verified.	Marla Schwarber (b) (4) (b) (4)	09 Dec 2020 21:48:07
User entered 'No (N)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	09 Dec 2020 21:48:07
User opened query 'Per DM CLR: Please confirm if this is used as Prophylaxis. If not, please review and update response if this should be changed. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:23:33
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
DataPoint Un-verified.	Andrea Wendrow (b) (4)	18 Nov 2020 23:09:07
User entered 'FEVER associated with COVID infection' reason for change: Per Query Resolution	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:09:07
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'FEVER'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '500'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'as needed (PRN)'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	28 Sep 2020 18:09:32
User entered '27 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:09:32
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	28 Sep 2020 18:08:58
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
DataPoint Un-verified.	Andrea Wendrow (b) (4)	18 Nov 2020 23:05:25
User entered 'No (N)' reason for change: New Information	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:05:25
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
DataPoint Un-verified.	Andrea Wendrow (b) (4)	18 Nov 2020 23:05:25
User entered '01 Oct 2020' reason for change: New Information	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:05:25
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 18:09:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 18:09:32
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	28 Sep 2020 18:09:32
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 18:08:58
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User entered empty.	System	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User entered empty.	System	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:45:47
User entered empty.	System	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:19:41
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 Sep 2020 21:19:41
Data point term sent to Coder	System	22 Sep 2020 21:19:00
User entered 'pantoprazole'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:08:58
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:47:46
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:57:17
User entered 'gerd'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '40'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '01 Jan 2018'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
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: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 20:50:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 20:50:00
Data point term sent to Coder Coding entries removed.	System Andrea Wendrow (b) (4)	18 Nov 2020 23:09:43 18 Nov 2020 23:09:42
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: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 06:46:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 06:46:39
Data point term sent to Coder Coding entries removed.	System Diana Bahena (b) (4)	09 Nov 2020 17:27:37 09 Nov 2020 17:26:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
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: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 03:18:28

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\202003. Data point term sent to Coders Coding entries removed.	Coder Import (b) (4) (b) (4) System Andrea Wendrow (b) (4) (b) (4)	06 Nov 2020 03:18:28 06 Nov 2020 03:17:29 06 Nov 2020 03:17:23
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: NAPROXEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 23:12:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. Data point term sent to Coders Coding entries removed.	Coder Import (b) (4) (b) (4) System Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 23:12:56 01 Oct 2020 20:27:13 01 Oct 2020 20:26:39
User entered 'NAPROXEN' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:26:39
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: NAPROXEN, PRODUCTS YNOMY: NAPROXENE [NAPROXEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 05:36:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. Data point term sent to Coders User entered 'Naproxene'	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	29 Sep 2020 05:36:48 28 Sep 2020 18:10:56 28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User closed query 'Per DM CLR: Please confirm if this is used as Prophylaxis. If not, please review and update response if this should be changed. Otherwise, please provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 07:21:18
Query 'Per DM CLR: Please confirm if this is used as Prophylaxis. If not, please review and update response if this should be changed. Otherwise, please provide clarification.' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	09 Dec 2020 21:49:11
DataPoint Un-verified.	Marla Schwarber (b) (4) (b) (4)	09 Dec 2020 21:49:03
User entered 'No (N)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	09 Dec 2020 21:49:03
User opened query 'Per DM CLR: Please confirm if this is used as Prophylaxis. If not, please review and update response if this should be changed. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:24:17
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'MYALGIAS, ARTHRALGIAS associated with covid infection' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	18 Nov 2020 23:09:42
DataPoint Un-verified.	Diana Bahena (b) (4)	09 Nov 2020 17:26:42
User entered 'Myalgias, arthralgias' reason for change: Data Entry Error	Diana Bahena (b) (4)	09 Nov 2020 17:26:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'FEVER' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	06 Nov 2020 03:17:23
User entered 'treat fever'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '220'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'as needed (PRN)'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '24 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 20:26:39
User entered '27 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 11:54:06
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with '-----thank you.	(b) (4), (b) (6)	12 Jan 2021 20:01:16
corrected.-----' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	12 Jan 2021 20:00:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 20:00:55
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:09:06
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '27 Sep 2020' reason for change: Data Entry Error	(b) (4)	12 Jan 2021 20:04:33
DataPoint Un-verified.	(b) (4), (b) (6)	12 Jan 2021 20:00:55
User entered '9 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 20:00:55
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Note that solicited sympoms should be related to IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 11:54:09
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Note that solicited sympoms should be related to IP admin. Please review and update as appropriate. Otherwise, provide clarification.' answered with '-----thank you. corrected.-----' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 20:01:20
DataPoint Un-verified.	(b) (4), (b) (6)	12 Jan 2021 20:00:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 20:00:55

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Note that solicited symptoms should be related to IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:09:45
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary. Please note that this CM was given at Day 3 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF, and update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:19:41
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary. Please note that this CM was given at Day 3 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF, and update this field to No. Else, provide clarification.' answered with 'reviewed and updated' (Site from DM).	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 17:26:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary. Please note that this CM was given at Day 3 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF, and update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:38:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 20:26:39
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User entered empty.	System	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User entered empty.	System	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:11
User entered empty.	System	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 07:42:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 07:42:54
Data point term sent to Coder	System	18 Nov 2020 16:37:19
User entered '2nd Dose of Shingles Vaccine'	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'Prophylaxis'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'UNK'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'Other (OTHER)'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'UNK'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'once (ONCE)'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered empty.	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'Intramuscular (INTRAMUSCULAR)'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered empty.	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered '10 Nov 2020'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered '0'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'No (N)'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:13:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered '10 Nov 2020'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'No (N)'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:13:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User entered empty.	System	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User entered empty.	System	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:16
User entered empty.	System	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:15:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:15:53
Data point term sent to Coder	System	18 Nov 2020 23:14:47
User entered 'azithromycin'	Andrea Wendrow (b) (4) (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:35:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'No (N)'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'cough from COVID'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered '250'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'mg (mg)'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered empty.	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'once daily (QD)'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered empty.	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'Oral (ORAL)'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:35:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered empty.	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered '05 Oct 2020'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered '0'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:35:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'No (N)'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:35:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered '09 Oct 2020'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:35:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'No (N)'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	(b) (4) Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:35:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User entered '1'	System	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User entered '1'	System	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:21
User entered '804 (804)'	System	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	(b) (4) Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:43:58

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:07:46
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:28:43

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Visit 2 Day 29 (VISIT2)'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'I'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'I'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'I'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'I'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

US3492237

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'I'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

US3492237

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'I'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

US3492237

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'I'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'I'	Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '27 Oct 2020'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'I'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

US3492237

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

US3492237

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

US3492237

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

US3492237

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

US3492237

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

US3492237

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'I'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

US3492237

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

US3492237

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

US3492237

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:43:58

[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'I'	(b) (4) Andrea Wendrow (b) (4)	14 Dec 2020 19:40:01

US3492237

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:43:58

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:25:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered '28 Sep 2020'	Andrea Wendrow (b) (4)	12 Oct 2020 05:11:58

US3492237

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:43:58

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:25:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered 'Due to SARS-COV-2 (COVID)'	Andrea Wendrow (b) (4)	12 Oct 2020 05:11:58

US3492237

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:43:58

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:25:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:22
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	12 Oct 2020 05:11:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:32
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:28
User entered 'USA-US101-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Richard'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Novak'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered '808 S. Wood St'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Chicago'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'IL'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered '60612'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 00:00:41
User entered 'US'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
	(b) (4)	
User entered '3'	System	09 Nov 2020 18:26:23
User entered '2'	System	03 Nov 2020 00:00:53
User entered '1'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:32
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:28
User entered	System	02 Oct 2020 12:21:58
'USA-US101-2020-MRNA-1273-P301000002'		

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

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Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Richard'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Novak'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered '808 S. Wood St'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Chicago'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'IL'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered '60612'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 00:00:41
User entered 'US'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
	(b) (4)	
User entered '3'	System	09 Nov 2020 18:26:23
User entered '2'	System	03 Nov 2020 00:00:53
User entered '1'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:43:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
User entered '02/Oct/2020 12:22'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:43:58

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.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 00:00:41
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:32
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:28
User entered 'USA-US101-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Richard'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Novak'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered '808 S. Wood St'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Chicago'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'IL'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered '60612'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 00:00:41
User entered 'US'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
	(b) (4)	
User entered '3'	System	09 Nov 2020 18:26:23
User entered '2'	System	03 Nov 2020 00:00:53
User entered '1'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:43:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
User entered '03/Nov/2020 00:00'	System	03 Nov 2020 00:00:53

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:43:58

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.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:25:28
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 00:00:53

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:32
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:28
User entered 'USA-US101-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Richard'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Novak'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered '808 S. Wood St'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Chicago'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'IL'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered '60612'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 00:00:41
User entered 'US'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
	(b) (4)	
User entered '3'	System	09 Nov 2020 18:26:23
User entered '2'	System	03 Nov 2020 00:00:53
User entered '1'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:43:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:05:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered '09/Nov/2020 13:26'	(b) (4) System	09 Nov 2020 18:26:23

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:43:58

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)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:05:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:16:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:26:23