

US3492242 (Prod: UIC Project WISH CRS)

Generated By: KC Joubran

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US3492242

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 04:17:35

Generated On: 11 Aug 2021 22:45:27

[Participant ID](#)

US3492242

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

US3492242

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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 04:17:55

Generated On: 11 Aug 2021 22:45:27

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	29
Age Units	YEARS
Age (Derived)	29
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	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	True
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 04:17:55

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Date of Informed Consent (<i>dd MMM yyyy</i>)	23 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 04:17:55

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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 04:17:55

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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 04:17:55

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Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:17:55

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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>)	23 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:41 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 09:41
Height (<i>xxx.x</i>)	180 cm
Weight (<i>xxx.x</i>)	223 kg
BMI (<i>xxx.x</i>)	68.82716 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 04:17:55

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 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 04:17:55

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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 OFFICE

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 04:17:55

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 11 Aug 2021 22:45:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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 04:17:56

Generated On: 11 Aug 2021 22:45:27

What was the date of randomization? (dd MMM yyyy) 23 SEP 2020

What was the participant's randomization number? 146630

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 04:17:56

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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 04:17:56

Generated On: 11 Aug 2021 22:45:27

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	09:41 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 09:41
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	178 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 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 04:17:56

Generated On: 11 Aug 2021 22:45:27

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	10:46 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 10:46
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)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 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 04:17:56

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 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 04:17:56

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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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 10:46 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 10:46

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 04:17:56

Generated On: 11 Aug 2021 22:45:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 SEP 2020
Collection time (00:00-23:59)	10:08 (24 HR)
Collection date and time (derived)	23 SEP 2020 10:08

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 11 Aug 2021 22:45:27

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:15	23 SEP 2020 10:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐
No ☒

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

PC Time Stamp 23 SEP 2020 11:08

PC Open Date & Time 23 SEP 2020 11:06

PC Close Date & Time 23 SEP 2020 13:36

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.9 °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	23 SEP 2020 18:34
PC Open Date & Time	23 SEP 2020 14:31
PC Close Date & Time	24 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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 00:03

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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 20:04

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

26 SEP 2020 19:49

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(5)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 12:28

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 20:02

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 12:03

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 11:09

PC Open Date & Time

23 SEP 2020 11:06

PC Close Date & Time

23 SEP 2020 13:36

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 18:21

PC Open Date & Time

23 SEP 2020 14:31

PC Close Date & Time

24 SEP 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 16:59

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 20:03

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 19:49

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 12:28

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 15:56

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 12:03

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 11:10
PC Open Date & Time	23 SEP 2020 11:06
PC Close Date & Time	23 SEP 2020 13:36

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 18:22
PC Open Date & Time	23 SEP 2020 14:31
PC Close Date & Time	24 SEP 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:27

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 16:59
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:27

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 20:03
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:27

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 19:49
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:27

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 15:56
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:27

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 12:04
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:45:27

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

30 SEP 2020 12:01

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:45:27

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 01 OCT 2020 23:59

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 30 SEP 2020 12:01

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3492242

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 SEP 2020 12:01
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3492242

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492242

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

IN ILLNESS VISIT PHASE

If Contact Not Made, please provide Comments

US3492242

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492242

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

IN ILLNESS VISIT PHASE

If Contact Not Made, please provide Comments

US3492242

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492242

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 11 Aug 2021 22:45:27

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3492242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 11 Aug 2021 22:45:27

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment?

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?

US3492242

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 11 Aug 2021 22:45:27

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3492242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 11 Aug 2021 22:45:27

Collection date (dd MMM yyyy)

Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3492242

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492242

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

IN ILLNESS VISIT PHASE

If Contact Not Made, please provide Comments

US3492242

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492242

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

IN ILLNESS VISIT PHASE

If Contact Not Made, please provide Comments

US3492242

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492242

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492242

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492242

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 11 Aug 2021 22:45:27

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 VISIT3

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 11 Aug 2021 22:45:27

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3492242

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 11 Aug 2021 22:45:27

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3492242

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 11 Aug 2021 22:45:27

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3492242

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	24 NOV 2020 02:52:53
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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="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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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 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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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	14 DEC 2020 01:43:54
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 00:08:30
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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 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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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 <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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	09 JAN 2021 17:50:57
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 11:13:03
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	22 JAN 2021 00:02:58
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	01 FEB 2021 17:59:54
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	05 FEB 2021 00:13:10
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 00:14:05

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 01:54:00

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 01:23:49

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 12:29:08

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 00:02:47

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 00:29:53

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 01:10:31

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 09:27:16

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 00:09:11

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 19:37:36

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 01:32:03

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 257

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

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 271

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

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 327

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

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

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

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

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2021 00:01
Patient Cloud Close Date & Time	21 SEP 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 DEC 2021 00:01
Patient Cloud Close Date & Time	07 DEC 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 FEB 2022 00:01
Patient Cloud Close Date & Time	15 FEB 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 523

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 537

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 572

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

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

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

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

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

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

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 ☐

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 586

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 635

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 642

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 656

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

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

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

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

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

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

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 ☐

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

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23 AUG 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

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26 AUG 2022 00:01

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30 AUG 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

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06 SEP 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

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09 SEP 2022 00:01

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13 SEP 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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20 SEP 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

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23 SEP 2022 00:01

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27 SEP 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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04 OCT 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

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11 OCT 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

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14 OCT 2022 00:01

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18 OCT 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

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25 OCT 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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28 OCT 2022 00:01

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01 NOV 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

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08 NOV 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2022 23:59

US3492242

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:45:27

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		07 MAR 2021 12:28:52

US3492242

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492242

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492242

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492242

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492242

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:53:47

Generated On: 11 Aug 2021 22:45:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492242

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:53:47

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492242

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:53:47

Generated On: 11 Aug 2021 22:45:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492242

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:53:47

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492242

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 30 Apr 2021 21:45:25

Generated On: 11 Aug 2021 22:45:27

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

Visit date (dd MMM yyyy)	30 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
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US3492242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Apr 2021 21:45:25

Generated On: 11 Aug 2021 22:45:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 APR 2021
Time of assessment (00:00-23:59)	11:52 (24 HR)
Vital Signs Date and Time (derived)	30 APR 2021 11:52
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)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	186 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492242

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Apr 2021 21:45:25

Generated On: 11 Aug 2021 22:45:27

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3492242

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Apr 2021 21:45:25

Generated On: 11 Aug 2021 22:45:27

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

Collection date (dd MMM yyyy)	30 APR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	12:17 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	30 APR 2021 12:17
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US3492242

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 30 Apr 2021 21:45:25

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492242

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492242

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 15 Feb 2021 04:17:53

Generated On: 11 Aug 2021 22:45:27

Date of Contact	3 OCT 2020
Time of Contact	09:00
Date and Time of Contact (derived)	3 OCT 2020 09:00
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>

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 SEP 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 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 03 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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 ☐

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 SEP 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	1 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 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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Form: Symptom Log (4)

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

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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 03 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	2 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 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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Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 16:32:38

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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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Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	3 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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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Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 16:32:38

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

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	4 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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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Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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 03 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 03 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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 03 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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 ☐

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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 03 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" 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 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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EAB) (1725)

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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 ☐

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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 ☐

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

Date	11 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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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Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input 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 03 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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 03 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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 ☐

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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 ☐

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

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

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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 ☐

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input 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 checked="" 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 03 Oct 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 03 Oct 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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 03 Oct 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input 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 checked="" 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 03 Oct 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 03 Oct 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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 03 Oct 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input 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 checked="" 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 03 Oct 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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 ☐

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input 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 checked="" 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 03 Oct 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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 ☐

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input 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 checked="" 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 03 Oct 2020

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

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 ☐

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 15 Feb 2021 04:17:53

Generated On: 11 Aug 2021 22:45:27

Date of Visit 05 OCT 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Date of Test 05 OCT 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Feb 2021 04:17:54

Generated On: 11 Aug 2021 22:45:27

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 _____

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Feb 2021 04:17:54

Generated On: 11 Aug 2021 22:45:27

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 03 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Feb 2021 04:17:54

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 15 Feb 2021 04:17:54

Generated On: 11 Aug 2021 22:45:27

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3492242

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 15 Feb 2021 04:17:54

Generated On: 11 Aug 2021 22:45:27

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	7 OCT 2020
Day 5	Yes	9 OCT 2020
Day 7	Yes	11 OCT 2020
Day 9	Yes	13 OCT 2020
Day 14	Yes	18 OCT 2020
Day 21	Yes	25 OCT 2020
Day 28	No	

US3492242

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 OCT 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

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 OCT 2020
Time of assessment (00:00-23:59)	12:35 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 12:35
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	170 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492242

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 OCT 2020

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

US3492242

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 04:17:54

Generated On: 11 Aug 2021 22:45:27

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

05 OCT 2020

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:17:36

Generated On: 11 Aug 2021 22:45:27

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 SICKD28

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:17:36

Generated On: 11 Aug 2021 22:45:27

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:17:36

Generated On: 11 Aug 2021 22:45:27

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3492242

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 04:17:36

Generated On: 11 Aug 2021 22:45:27

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3492242

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

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

Visit date (dd MMM yyyy)	2 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3492242

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 01:53:47

Generated On: 11 Aug 2021 22:45:27

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

US3492242

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

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

US3492242

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

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)	2 FEB 2021
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 12:15
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	168 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3492242

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

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)	2 FEB 2021
Time of assessment (00:00-23:59)	12:55 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 12:55
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3492242

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

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 FEB 2021

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

US3492242

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

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 2 FEB 2021

What was the treatment time? (00:00-23:59) 12:42 (24 HR)

Treatment Date and Time (derived) 2 FEB 2021 12:42

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

US3492242

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3492242

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 FEB 2021
Collection time (00:00 - 23:59)	12:05
Collection Date and Time (derived)	2 FEB 2021 12:05

US3492242

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492242

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492242

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

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

US3492242

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:53:47

Generated On: 11 Aug 2021 22:45:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 01:53:47

Generated On: 11 Aug 2021 22:45:27

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 MAR 2021
Time of assessment (00:00-23:59)	11:24 (24 HR)
Vital Signs Date and Time (derived)	4 MAR 2021 11:24
Temperature (xxx.x)	36.0 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	177 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	117 mmHg
Diastolic Blood Pressure units	MMHG

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 01:53:47

Generated On: 11 Aug 2021 22:45:27

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)	4 MAR 2021
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	4 MAR 2021 11:55
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TMPANIC
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	169 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3492242

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:53:47

Generated On: 11 Aug 2021 22:45:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 MAR 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: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 01:53:47

Generated On: 11 Aug 2021 22:45:27

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 4 MAR 2021

What was the treatment time? (00:00-23:59) 11:53 (24 HR)

Treatment Date and Time (derived) 4 MAR 2021 11:53

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: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:53:47

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492242

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:53:47

Generated On: 11 Aug 2021 22:45:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 MAR 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-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:53:47

Generated On: 11 Aug 2021 22:45:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 30 Apr 2021 21:45:24

Generated On: 11 Aug 2021 22:45:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

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Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Apr 2021 21:45:24

Generated On: 11 Aug 2021 22:45:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 APR 2021
Time of assessment (<i>00:00-23:59</i>)	11:52 (24 HR)
Vital Signs Date and Time (derived)	30 APR 2021 11:52
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	186 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Apr 2021 21:45:24

Generated On: 11 Aug 2021 22:45:27

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3492242

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Apr 2021 21:45:24

Generated On: 11 Aug 2021 22:45:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 APR 2021
Collection time (00:00-23:59)	12:17 (24 HR)
Collection date and time (derived)	30 APR 2021 12:17

US3492242

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 04:17:36

Generated On: 11 Aug 2021 22:45:27

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Feb 2021 04:17:35

Generated On: 11 Aug 2021 22:45:27

AEID	USA-US101-2020-MRNA-1273-P30 1000003
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)	29 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)	22 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"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Feb 2021 04:17:35

Generated On: 11 Aug 2021 22:45:27

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" 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	
NEGATIVE BASELINE SARS COVID-19	
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 (5)

Data signed: (b) (4) 15 Feb 2021 04:17:35

Generated On: 11 Aug 2021 22:45:27

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 15 Feb 2021 04:17:35

Generated On: 11 Aug 2021 22:45:27

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 04:17:36

Generated On: 11 Aug 2021 22:45:27

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) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Name of Medication THERAFLU {ACETAMINOPHEN,
DEXTROMETHORPHAN,
PHENYLEPHRINE}

Prophylaxis Yes ☐
No ☒

Indication COUGH LATER FOUND TO BE
RELATED TO COVID-19

Dose per administration 500/20/10

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
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 (3)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication WORSENING HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	06 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Name of Medication ROBITUSSIN DM
(DEXTROMETHORPHAN HBR 20
MG/GUAIFENESIN 200 MG)

Prophylaxis Yes ☐
No ☒

Indication COUGH, RELATED TO COVID 19
INFECTION

Dose per administration 20/200

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 ☐

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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) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

Name of Medication NYQUIL COLD AND FLU
(ACETAMINOPHEN 650
MG/DEXTROMETHORPHAN
HBR 30 MG/DOXYLAMINE
SUCCINATE 12.5 MG PER 30
MIL)

Prophylaxis Yes ☐
No ☒

Indication COUGH, RELATED TO COVID 19
INFECTION

Dose per administration 650/30/12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 16:32:38

Generated On: 11 Aug 2021 22:45:27

	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 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"/>

US3492242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 04:17:36

Generated On: 11 Aug 2021 22:45:27

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3492242

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 15 Feb 2021 04:17:54

Generated On: 11 Aug 2021 22:45:27

Date of dosing discontinuation (dd MMM yyyy) 5 OCT 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

US3492242

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:45:27

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

SAEID	USA-US101-2020-MRNA-1273-P301000003
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)	4

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

SAEID	USA-US101-2020-MRNA-1273-P301000003
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)	4
Date of submission (Pre-filled from custom function)	04/OCT/2020 10:21
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

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

SAEID	USA-US101-2020-MRNA-1273-P301000003
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)	4
Date of submission (Pre-filled from custom function)	03/NOV/2020 00:06
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

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

SAEID	USA-US101-2020-MRNA-1273-P301000003
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)	4
Date of submission (Pre-filled from custom function)	09/NOV/2020 20:20
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

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 11 Aug 2021 22:45:27

SAEID	USA-US101-2020-MRNA-1273-P301000003
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)	4
Date of submission (Pre-filled from custom function)	18/NOV/2020 20:24
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

US3492242 (Prod: UIC Project WISH CRS)

US3492242

Form: Participant Creation

Generated On: 11 Aug 2021 22:45:27

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'US3492242'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 14:34:55

US3492242

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:16:28

US3492242

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '23 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 14:34:56

US3492242

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:16:28

US3492242

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered 'SCRN'	System	23 Sep 2020 15:16:28

US3492242

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:27

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered (b) (6) 1991'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 14:34:57

US3492242

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:27

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '29'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:17:08

US3492242

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:27

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered 'YEARS'	System	23 Sep 2020 15:17:08

US3492242

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:27

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered '29'	System	23 Sep 2020 15:18:04

US3492242

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:27

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:17:08

US3492242

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:27

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:17:08

US3492242

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:27

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:17:08

US3492242

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:27

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:17:08

US3492242

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:27

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:17:08

US3492242

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:27

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:17:08

US3492242

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:27

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:17:08

US3492242

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:17:08

US3492242

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:27

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:17:08

US3492242

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:27

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:17:08

US3492242

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:45:27

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:17:08

US3492242

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:27

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:18:04

US3492242

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered 'Sep 2020'	System	23 Sep 2020 15:18:04

US3492242

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered '2020'	System	23 Sep 2020 15:18:04

US3492242

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:27

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:18:04

US3492242

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:18:04

US3492242

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:18:04

US3492242

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:27

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:18:04

US3492242

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:27

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:18:04

US3492242

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:27

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 14:34:56

US3492242

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:45:27

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered 'I'	System	23 Sep 2020 15:18:10

US3492242

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:18:10

US3492242

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:45:27

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:18:19

US3492242

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 15:21:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 15:21:34
Data point term sent to Coder	System	23 Sep 2020 15:20:43
User entered 'Hypertension'	(b) (4), (b) (6)	23 Sep 2020 15:20:36

US3492242

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:20:36

US3492242

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:20:36

US3492242

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:20:36

US3492242

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:20:36

US3492242

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:20:36

US3492242

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered 'Jan 2018'	System	23 Sep 2020 15:20:36

US3492242

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered '2018'	System	23 Sep 2020 15:20:36

US3492242

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered empty.	System	23 Sep 2020 15:20:36

US3492242

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered empty.	System	23 Sep 2020 15:20:36

US3492242

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 15:22:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 15:22:38
Data point term sent to Coder	System	23 Sep 2020 15:21:45
User entered 'Sleep Apnea'	(b) (4), (b) (6)	23 Sep 2020 15:21:04

US3492242

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:04

US3492242

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:04

US3492242

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:04

US3492242

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:04

US3492242

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:04

US3492242

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered 'Jan 2016'	System	23 Sep 2020 15:21:04

US3492242

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered '2016'	System	23 Sep 2020 15:21:04

US3492242

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered empty.	System	23 Sep 2020 15:21:04

US3492242

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered empty.	System	23 Sep 2020 15:21:04

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:20:05

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:20:05

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '09:41'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:20:05

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered '23 Sep 2020 09:41'	System	23 Sep 2020 15:20:05

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '180' cm	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:20:05
DataPoint set to visible.	System	23 Sep 2020 15:18:10

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:03
Query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' answered with 'Real patient weight' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 15:29:55
User entered '223' kg reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Sep 2020 15:29:48
User opened query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	System	23 Sep 2020 15:20:05
User entered '188' kg	(b) (4), (b) (6)	23 Sep 2020 15:20:05
DataPoint set to visible.	System	23 Sep 2020 15:18:10

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered '68.82716'	System	23 Sep 2020 15:29:48
User entered '58.02469'	System	23 Sep 2020 15:20:05
DataPoint set to visible.	System	23 Sep 2020 15:18:10

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered 'kg/m2'	System	23 Sep 2020 15:20:05
DataPoint set to visible.	System	23 Sep 2020 15:18:10

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:20:05

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:20:05

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:20:05

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:20:05

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered 'bpm'	System	23 Sep 2020 15:20:05

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:20:05

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered 'breaths/min'	System	23 Sep 2020 15:20:05

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:20:05

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered 'mmHg'	System	23 Sep 2020 15:20:05

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:20:05

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User entered 'mmHg'	System	23 Sep 2020 15:20:05

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42

US3492242

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42

US3492242

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:16

US3492242

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:16

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

[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 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'office'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:45:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:21:57

US3492242

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:22:09

US3492242

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:22:09

US3492242

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:22:09

US3492242

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'VISIT1'	System	23 Sep 2020 15:22:09

US3492242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '23 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 15:09:24

US3492242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '146630'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 15:09:24

US3492242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 15:09:24

US3492242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:27

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:22:21

US3492242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:27

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:22:21

US3492242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:27

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:22:21

US3492242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:22:21

US3492242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:27

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:22:21

US3492242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:22:21
DataPoint set to visible.	System	23 Sep 2020 15:18:04

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 05:16:32
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'updated' (Site from DM).	Lorna Sanchez McCann (b) (4)	05 Oct 2020 18:43:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	Lorna Sanchez McCann (b) (4)	05 Oct 2020 18:42:49
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:14:20
User entered '180' cm	(b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	05 Oct 2020 18:42:49
User closed query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 13:50:08
Query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' answered with 'Real patient weight ' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 15:29:27
User entered '223' kg reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Sep 2020 15:29:08
User opened query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	System	23 Sep 2020 15:24:18
User entered '188' kg	(b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 05:16:32
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'updated' (Site from DM).	Lorna Sanchez McCann (b) (4)	05 Oct 2020 18:43:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	Lorna Sanchez McCann (b) (4)	05 Oct 2020 18:42:49
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:14:20
User entered '180' cm	(b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	05 Oct 2020 18:42:49
User closed query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 13:50:08
Query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' answered with 'Real patient weight ' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 15:29:27
User entered '223' kg reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Sep 2020 15:29:08
User opened query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	System	23 Sep 2020 15:24:18
User entered '188' kg	(b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '09:41'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered '23 Sep 2020 09:41'	System	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '99.1' F	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Tympanic'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '93'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'bpm'	System	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '18'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:24:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'breaths/min'	System	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '178'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:24:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'mmHg'	System	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '94'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'mmHg'	System	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 05:16:32
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'updated' (Site from DM).	Lorna Sanchez McCann (b) (4)	05 Oct 2020 18:43:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	Lorna Sanchez McCann (b) (4)	05 Oct 2020 18:42:49
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:14:20
User entered '180' cm	(b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	05 Oct 2020 18:42:49
User closed query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 13:50:08
Query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' answered with 'Real patient weight ' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 15:29:27
User entered '223' kg reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Sep 2020 15:29:08
User opened query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	System	23 Sep 2020 15:24:18
User entered '188' kg	(b) (4), (b) (6)	23 Sep 2020 15:24:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
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	23 Sep 2020 15:53:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	23 Sep 2020 15:53:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Sep 2020 15:24:18
	(b) (4), (b) (6)	23 Sep 2020 15:24:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4)	23 Sep 2020 15:53:55
User entered empty.	Gizelle Alvarez (b) (4)	23 Sep 2020 15:24:18
	(b) (4), (b) (6)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '10:46' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	23 Sep 2020 15:53:55
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:24:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered '23 Sep 2020 10:46'	System	23 Sep 2020 15:53:55
User entered empty.	System	23 Sep 2020 15:24:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '36.6' C reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	23 Sep 2020 15:53:55
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:24:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	23 Sep 2020 15:53:55
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:24:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'TYMPANIC' reason for change: Data Entry Error	(b) (4)	23 Sep 2020 15:53:55
User entered empty.	Gizelle Alvarez (b) (4)	23 Sep 2020 15:24:18
	(b) (4), (b) (6)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '90' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	23 Sep 2020 15:53:55
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'bpm'	System	23 Sep 2020 15:53:55
User entered empty.	System	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '22' reason for change: Data Entry Error	(b) (4)	23 Sep 2020 15:53:55
User entered empty.	Gizelle Alvarez (b) (4)	23 Sep 2020 15:24:18
	(b) (4), (b) (6)	

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'breaths/min'	System	23 Sep 2020 15:53:55
User entered empty.	System	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '158' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	23 Sep 2020 15:53:55
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'mmHg'	System	23 Sep 2020 15:53:55
User entered empty.	System	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '92' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	23 Sep 2020 15:53:55
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'mmHg'	System	23 Sep 2020 15:53:55
User entered empty.	System	23 Sep 2020 15:24:18

US3492242

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:32:34

US3492242

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:32:34

US3492242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	23 Sep 2020 15:48:52

US3492242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Gizelle Alvarez (b) (4)	23 Sep 2020 15:48:52

US3492242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Gizelle Alvarez (b) (4)	23 Sep 2020 15:48:52

US3492242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 15:48:52

US3492242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '23 Sep 2020'	Gizelle Alvarez (b) (4)	23 Sep 2020 15:48:52

US3492242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '10:46'	Gizelle Alvarez (b) (4)	23 Sep 2020 15:48:52

US3492242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered '23 Sep 2020 10:46'	System	23 Sep 2020 15:48:52

US3492242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Left Arm (LEFT ARM)'	Gizelle Alvarez (b) (4)	23 Sep 2020 15:48:52

US3492242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'ONCE'	System	23 Sep 2020 15:48:52

US3492242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 15:48:52

US3492242

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	23 Sep 2020 15:49:48

US3492242

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '23 Sep 2020'	Gizelle Alvarez (b) (4)	23 Sep 2020 15:49:48

US3492242

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '10:08'	Gizelle Alvarez (b) (4)	23 Sep 2020 15:49:48

US3492242

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered '23 Sep 2020 10:08'	System	23 Sep 2020 15:49:48

US3492242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:45:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '23 Sep 2020'	Gizelle Alvarez (b) (4)	23 Sep 2020 15:50:04

US3492242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:45:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Gizelle Alvarez (b) (4)	23 Sep 2020 15:50:04

US3492242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:45:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	23 Sep 2020 15:50:04

US3492242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:45:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '10:15'	Gizelle Alvarez (b) (4)	23 Sep 2020 15:50:04

US3492242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:45:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered '23 Sep 2020 10:15'	System	23 Sep 2020 15:50:04

US3492242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:45:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Gizelle Alvarez (b) (4) (b) (4)	23 Sep 2020 15:50:04

US3492242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:45:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	Gizelle Alvarez (b) (4)	23 Sep 2020 15:50:04

US3492242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:45:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Gizelle Alvarez (b) (4)	23 Sep 2020 15:50:04

US3492242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:45:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	23 Sep 2020 15:50:04

US3492242

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query 'Per CDM re-query: Response noted, however, per CCGs pages 18-19, Visit 2 should still be entered. Please review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 11:04:40
User entered 'No (N)' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	10 Nov 2020 20:32:31
Query 'Per CDM re-query: Response noted, however, per CCGs pages 18-19, Visit 2 should still be entered. Please review and update as appropriate.' answered with 'participant's treatment was discontinued. visit 2 did not occur.' (Site from DM).	Lorna Sanchez McCann (b) (4)	10 Nov 2020 20:32:26
User opened query 'Per CDM re-query: Response noted, however, per CCGs pages 18-19, Visit 2 should still be entered. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:19:03
User closed query 'Per CDM: 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)	09 Nov 2020 10:19:03
Query 'Per CDM: 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 'Subject in Illness Visit track' (Site from DM).	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 19:36:03
User opened query 'Per CDM: 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 14:20:15
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	23 Sep 2020 15:50:08

US3492242

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	10 Nov 2020 20:32:31
User entered '1'	System	23 Sep 2020 15:50:08

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:08:12', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'e9bc1a32-672b-45dc-9273-c7693845ee05'	System	23 Sep 2020 16:08:41
User entered 'Yes (Y)'	System	23 Sep 2020 16:08:41

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:08:19', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'e9bc1a32-672b-45dc-9273-c7693845ee05'	System	23 Sep 2020 16:08:41
User entered '97.8'	System	23 Sep 2020 16:08:41

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:08:29', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'e9bc1a32-672b-45dc-9273-c7693845ee05'	System	23 Sep 2020 16:08:41
User entered 'No (N)'	System	23 Sep 2020 16:08:41

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:08:36', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'e9bc1a32-672b-45dc-9273-c7693845ee05'	System	23 Sep 2020 16:08:41
User entered '23 Sep 2020 11:08'	System	23 Sep 2020 16:08:41

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '23 Sep 2020 11:06'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '23 Sep 2020 13:36'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:33:27', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '027aa4be-afa4-42f1-9c0b-d385ad54737d'	System	23 Sep 2020 23:34:10
User entered 'Yes (Y)'	System	23 Sep 2020 23:34:10

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:34:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '027aa4be-afa4-42f1-9c0b-d385ad54737d'	System	23 Sep 2020 23:34:10
User entered '96.9'	System	23 Sep 2020 23:34:10

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:34:04', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '027aa4be-afa4-42f1-9c0b-d385ad54737d'	System	23 Sep 2020 23:34:10
User entered 'No (N)'	System	23 Sep 2020 23:34:10

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:34:09', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '027aa4be-afa4-42f1-9c0b-d385ad54737d'	System	23 Sep 2020 23:34:10
User entered '23 Sep 2020 18:34'	System	23 Sep 2020 23:34:10

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '23 Sep 2020 14:31'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 2'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T00:03:39', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4f7cc7cc-bdf0-442f-9d1f-fd2c11c2b482'	System	25 Sep 2020 05:03:56
User entered 'Yes (Y)'	System	25 Sep 2020 05:03:56

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T00:03:46', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4f7cc7cc-bdf0-442f-9d1f-fd2c11c2b482'	System	25 Sep 2020 05:03:56
User entered '98.1'	System	25 Sep 2020 05:03:56

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T00:03:51', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4f7cc7cc-bdf0-442f-9d1f-fd2c11c2b482'	System	25 Sep 2020 05:03:56
User entered 'No (N)'	System	25 Sep 2020 05:03:56

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T00:03:54', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4f7cc7cc-bdf0-442f-9d1f-fd2c11c2b482'	System	25 Sep 2020 05:03:56
User entered '25 Sep 2020 00:03'	System	25 Sep 2020 05:03:56

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 3'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:04:22', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'dd770c2c-94dd-407e-b894-a4a9071ec58a'	System	26 Sep 2020 01:14:35
User entered 'Yes (Y)'	System	26 Sep 2020 01:14:35

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:04:31', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'dd770c2c-94dd-407e-b894-a4a9071ec58a' User entered '98.1'	System	26 Sep 2020 01:14:35
	System	26 Sep 2020 01:14:35

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:04:34', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'dd770c2c-94dd-407e-b894-a4a9071ec58a'	System	26 Sep 2020 01:14:35
User entered 'No (N)'	System	26 Sep 2020 01:14:35

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:04:39', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'dd770c2c-94dd-407e-b894-a4a9071ec58a'	System	26 Sep 2020 01:14:35
User entered '25 Sep 2020 20:04'	System	26 Sep 2020 01:14:35

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 4'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:47:41', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '73fd4315-9c33-4d4d-ad5e-5a2e1fe7db35'	System	27 Sep 2020 00:49:23
User entered 'Yes (Y)'	System	27 Sep 2020 00:49:23

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:49:11', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '73fd4315-9c33-4d4d-ad5e-5a2e1fe7db35'	System	27 Sep 2020 00:49:23
User entered '98.7'	System	27 Sep 2020 00:49:23

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:49:14', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '73fd4315-9c33-4d4d-ad5e-5a2e1fe7db35'	System	27 Sep 2020 00:49:23
User entered 'No (N)'	System	27 Sep 2020 00:49:23

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:49:18', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '73fd4315-9c33-4d4d-ad5e-5a2e1fe7db35'	System	27 Sep 2020 00:49:23
User entered '26 Sep 2020 19:49'	System	27 Sep 2020 00:49:23

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 5'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:27:54', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '181c34af-9039-46af-acb5-de656d820ea0'	System	27 Sep 2020 17:28:08
User entered 'Yes (Y)'	System	27 Sep 2020 17:28:08

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:27:59', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '181c34af-9039-46af-acb5-de656d820ea0'	System	27 Sep 2020 17:28:08
User entered '97.3'	System	27 Sep 2020 17:28:08

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:28:02', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '181c34af-9039-46af-acb5-de656d820ea0'	System	27 Sep 2020 17:28:08
User entered 'No (N)'	System	27 Sep 2020 17:28:08

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:28:04', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '181c34af-9039-46af-acb5-de656d820ea0'	System	27 Sep 2020 17:28:08
User entered '27 Sep 2020 12:28'	System	27 Sep 2020 17:28:08

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 6'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T20:01:46', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '1aa69048-180f-4430-b5f7-c132ad248253'	System	29 Sep 2020 01:02:07
User entered 'Yes (Y)'	System	29 Sep 2020 01:02:07

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T20:01:51', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '1aa69048-180f-4430-b5f7-c132ad248253'	System	29 Sep 2020 01:02:07
User entered '98.4'	System	29 Sep 2020 01:02:07

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T20:01:53', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '1aa69048-180f-4430-b5f7-c132ad248253'	System	29 Sep 2020 01:02:07
User entered 'No (N)'	System	29 Sep 2020 01:02:07

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T20:02:02', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '1aa69048-180f-4430-b5f7-c132ad248253'	System	29 Sep 2020 01:02:07
User entered '28 Sep 2020 20:02'	System	29 Sep 2020 01:02:07

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 7'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:02:51', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '6546fd1f-c053-4b99-b0bd-2074a32fca71'	System	29 Sep 2020 17:03:18
User entered 'Yes (Y)'	System	29 Sep 2020 17:03:18

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:02:55', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '6546fd1f-c053-4b99-b0bd-2074a32fca71' User entered '99.3'	System	29 Sep 2020 17:03:18
	System	29 Sep 2020 17:03:18

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:03:10', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '6546fd1f-c053-4b99-b0bd-2074a32fca71'	System	29 Sep 2020 17:03:18
User entered 'No (N)'	System	29 Sep 2020 17:03:18

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:03:13', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '6546fd1f-c053-4b99-b0bd-2074a32fca71'	System	29 Sep 2020 17:03:18
User entered '29 Sep 2020 12:03'	System	29 Sep 2020 17:03:18

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:08:49', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'f188a777-5a2d-4f60-85ee-1898a53fa0cd'	System	23 Sep 2020 16:09:36
User entered 'None (1)'	System	23 Sep 2020 16:09:36

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:09:03', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'f188a777-5a2d-4f60-85ee-1898a53fa0cd'	System	23 Sep 2020 16:09:36
User entered 'No (N)'	System	23 Sep 2020 16:09:36

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:09:10', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'f188a777-5a2d-4f60-85ee-1898a53fa0cd'	System	23 Sep 2020 16:09:36
User entered 'No (N)'	System	23 Sep 2020 16:09:36

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:09:30', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'f188a777-5a2d-4f60-85ee-1898a53fa0cd'	System	23 Sep 2020 16:09:36
User entered 'None (1)'	System	23 Sep 2020 16:09:36

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:09:33', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'f188a777-5a2d-4f60-85ee-1898a53fa0cd'	System	23 Sep 2020 16:09:36
User entered '23 Sep 2020 11:09'	System	23 Sep 2020 16:09:36

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '23 Sep 2020 11:06'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '23 Sep 2020 13:36'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:21:34', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'b5880e49-eb01-4bba-807c-47b8cf6319b3'	System	23 Sep 2020 23:21:56
User entered 'None (1)'	System	23 Sep 2020 23:21:56

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:21:40', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'b5880e49-eb01-4bba-807c-47b8cf6319b3'	System	23 Sep 2020 23:21:56
User entered 'No (N)'	System	23 Sep 2020 23:21:56

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:21:45', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'b5880e49-eb01-4bba-807c-47b8cf6319b3'	System	23 Sep 2020 23:21:56
User entered 'No (N)'	System	23 Sep 2020 23:21:56

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:21:48', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'b5880e49-eb01-4bba-807c-47b8cf6319b3'	System	23 Sep 2020 23:21:56
User entered 'None (1)'	System	23 Sep 2020 23:21:56

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:21:52', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'b5880e49-eb01-4bba-807c-47b8cf6319b3'	System	23 Sep 2020 23:21:56
User entered '23 Sep 2020 18:21'	System	23 Sep 2020 23:21:56

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '23 Sep 2020 14:31'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 2'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-24T16:58:47', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'eacee57d-efeb-41c1-83e3-efdbab2dac39'	System	24 Sep 2020 21:59:11
User entered 'None (1)'	System	24 Sep 2020 21:59:11

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-24T16:58:50', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'eacee57d-efeb-41c1-83e3-efdbab2dac39'	System	24 Sep 2020 21:59:11
User entered 'No (N)'	System	24 Sep 2020 21:59:11

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-24T16:59:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'eacee57d-efeb-41c1-83e3-efdbab2dac39'	System	24 Sep 2020 21:59:11
User entered 'No (N)'	System	24 Sep 2020 21:59:11

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-24T16:59:04', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'eacee57d-efeb-41c1-83e3-efdbab2dac39'	System	24 Sep 2020 21:59:11
User entered 'None (1)'	System	24 Sep 2020 21:59:11

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-24T16:59:08', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'eacee57d-efeb-41c1-83e3-efdbab2dac39'	System	24 Sep 2020 21:59:11
User entered '24 Sep 2020 16:59'	System	24 Sep 2020 21:59:11

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 3'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:03:47', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '80951a0a-ff26-4c40-ac95-2d87236d6a3d'	System	26 Sep 2020 01:11:53
User entered 'None (1)'	System	26 Sep 2020 01:11:53

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:03:45', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '80951a0a-ff26-4c40-ac95-2d87236d6a3d'	System	26 Sep 2020 01:11:53
User entered 'No (N)'	System	26 Sep 2020 01:11:53

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:03:49', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '80951a0a-ff26-4c40-ac95-2d87236d6a3d'	System	26 Sep 2020 01:11:53
User entered 'No (N)'	System	26 Sep 2020 01:11:53

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:03:52', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '80951a0a-ff26-4c40-ac95-2d87236d6a3d'	System	26 Sep 2020 01:11:53
User entered 'None (1)'	System	26 Sep 2020 01:11:53

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:03:57', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '80951a0a-ff26-4c40-ac95-2d87236d6a3d'	System	26 Sep 2020 01:11:53
User entered '25 Sep 2020 20:03'	System	26 Sep 2020 01:11:53

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 4'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:49:30', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3f0a6f11-e0c2-466e-8d62-a9133f32536a'	System	27 Sep 2020 00:49:40
User entered 'None (1)'	System	27 Sep 2020 00:49:40

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:49:33', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3f0a6f11-e0c2-466e-8d62-a9133f32536a'	System	27 Sep 2020 00:49:40
User entered 'No (N)'	System	27 Sep 2020 00:49:40

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:49:35', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3f0a6f11-e0c2-466e-8d62-a9133f32536a'	System	27 Sep 2020 00:49:40
User entered 'No (N)'	System	27 Sep 2020 00:49:40

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:49:36', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3f0a6f11-e0c2-466e-8d62-a9133f32536a'	System	27 Sep 2020 00:49:40
User entered 'None (1)'	System	27 Sep 2020 00:49:40

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:49:39', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3f0a6f11-e0c2-466e-8d62-a9133f32536a'	System	27 Sep 2020 00:49:40
User entered '26 Sep 2020 19:49'	System	27 Sep 2020 00:49:40

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 5'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:28:21', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4e460c09-b04d-4fdd-8a0f-b0c1e4183603'	System	27 Sep 2020 17:28:30
User entered 'None (1)'	System	27 Sep 2020 17:28:30

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:28:23', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4e460c09-b04d-4fdd-8a0f-b0c1e4183603'	System	27 Sep 2020 17:28:30
User entered 'No (N)'	System	27 Sep 2020 17:28:30

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:28:25', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4e460c09-b04d-4fdd-8a0f-b0c1e4183603'	System	27 Sep 2020 17:28:30
User entered 'No (N)'	System	27 Sep 2020 17:28:30

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:28:26', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4e460c09-b04d-4fdd-8a0f-b0c1e4183603'	System	27 Sep 2020 17:28:30
User entered 'None (1)'	System	27 Sep 2020 17:28:30

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:28:28', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4e460c09-b04d-4fdd-8a0f-b0c1e4183603'	System	27 Sep 2020 17:28:30
User entered '27 Sep 2020 12:28'	System	27 Sep 2020 17:28:30

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 6'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T15:56:22', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'd7b0ef05-cca6-4dee-985a-b65f34517cdc'	System	28 Sep 2020 20:56:33
User entered 'None (1)'	System	28 Sep 2020 20:56:33

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T15:56:24', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'd7b0ef05-cca6-4dee-985a-b65f34517cdc'	System	28 Sep 2020 20:56:33
User entered 'No (N)'	System	28 Sep 2020 20:56:33

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T15:56:26', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'd7b0ef05-cca6-4dee-985a-b65f34517cdc'	System	28 Sep 2020 20:56:33
User entered 'No (N)'	System	28 Sep 2020 20:56:33

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T15:56:28', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'd7b0ef05-cca6-4dee-985a-b65f34517cdc'	System	28 Sep 2020 20:56:33
User entered 'None (1)'	System	28 Sep 2020 20:56:33

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T15:56:30', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'd7b0ef05-cca6-4dee-985a-b65f34517cdc'	System	28 Sep 2020 20:56:33
User entered '28 Sep 2020 15:56'	System	28 Sep 2020 20:56:33

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 7'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:03:16', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'fc1ccad0-8f2e-4057-9fac-58da2d051735'	System	29 Sep 2020 17:03:29
User entered 'None (1)'	System	29 Sep 2020 17:03:29

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:03:18', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'fc1ccad0-8f2e-4057-9fac-58da2d051735'	System	29 Sep 2020 17:03:29
User entered 'No (N)'	System	29 Sep 2020 17:03:29

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:03:20', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'fc1ccad0-8f2e-4057-9fac-58da2d051735'	System	29 Sep 2020 17:03:29
User entered 'No (N)'	System	29 Sep 2020 17:03:29

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:03:22', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'fc1ccad0-8f2e-4057-9fac-58da2d051735'	System	29 Sep 2020 17:03:29
User entered 'None (1)'	System	29 Sep 2020 17:03:29

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:03:24', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'fc1ccad0-8f2e-4057-9fac-58da2d051735'	System	29 Sep 2020 17:03:29
User entered '29 Sep 2020 12:03'	System	29 Sep 2020 17:03:29

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:09:45', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'f152225d-a2b3-47a7-a68f-c98bfac79f7c'	System	23 Sep 2020 16:10:42
User entered 'None (0)'	System	23 Sep 2020 16:10:42

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:10:29', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'f152225d-a2b3-47a7-a68f-c98bfac79f7c'	System	23 Sep 2020 16:10:42
User entered 'None (0)'	System	23 Sep 2020 16:10:42

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:10:28', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'f152225d-a2b3-47a7-a68f-c98bfac79f7c'	System	23 Sep 2020 16:10:42
User entered 'None (0)'	System	23 Sep 2020 16:10:42

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:10:28', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'f152225d-a2b3-47a7-a68f-c98bfac79f7c'	System	23 Sep 2020 16:10:42
User entered 'None (0)'	System	23 Sep 2020 16:10:42

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:10:27', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'f152225d-a2b3-47a7-a68f-c98bfac79f7c'	System	23 Sep 2020 16:10:42
User entered 'None (0)'	System	23 Sep 2020 16:10:42

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:10:26', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'f152225d-a2b3-47a7-a68f-c98bfac79f7c'	System	23 Sep 2020 16:10:42
User entered 'None (0)'	System	23 Sep 2020 16:10:42

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:10:25', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'f152225d-a2b3-47a7-a68f-c98bfac79f7c'	System	23 Sep 2020 16:10:42
User entered 'No (N)'	System	23 Sep 2020 16:10:42

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T11:10:37', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'f152225d-a2b3-47a7-a68f-c98bfac79f7c'	System	23 Sep 2020 16:10:42
User entered '23 Sep 2020 11:10'	System	23 Sep 2020 16:10:42

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '23 Sep 2020 11:06'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '23 Sep 2020 13:36'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:21:59', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '2a63324f-6bc3-4394-9f7c-b2d88eb8094c'	System	23 Sep 2020 23:22:35
User entered 'None (0)'	System	23 Sep 2020 23:22:35

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:22:03', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '2a63324f-6bc3-4394-9f7c-b2d88eb8094c'	System	23 Sep 2020 23:22:35
User entered 'None (0)'	System	23 Sep 2020 23:22:35

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:22:06', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '2a63324f-6bc3-4394-9f7c-b2d88eb8094c'	System	23 Sep 2020 23:22:35
User entered 'None (0)'	System	23 Sep 2020 23:22:35

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:22:08', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '2a63324f-6bc3-4394-9f7c-b2d88eb8094c'	System	23 Sep 2020 23:22:35
User entered 'None (0)'	System	23 Sep 2020 23:22:35

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:22:14', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '2a63324f-6bc3-4394-9f7c-b2d88eb8094c'	System	23 Sep 2020 23:22:35
User entered 'None (0)'	System	23 Sep 2020 23:22:35

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:22:16', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '2a63324f-6bc3-4394-9f7c-b2d88eb8094c'	System	23 Sep 2020 23:22:35
User entered 'None (0)'	System	23 Sep 2020 23:22:35

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:22:25', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '2a63324f-6bc3-4394-9f7c-b2d88eb8094c'	System	23 Sep 2020 23:22:35
User entered 'No (N)'	System	23 Sep 2020 23:22:35

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-23T18:22:33', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '2a63324f-6bc3-4394-9f7c-b2d88eb8094c'	System	23 Sep 2020 23:22:35
User entered '23 Sep 2020 18:22'	System	23 Sep 2020 23:22:35

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '23 Sep 2020 14:31'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 2'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-24T16:59:16', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'cb5e8e9d-3a4d-491a-b396-993a6b5101ae'	System	24 Sep 2020 21:59:36
User entered 'No interference with activity (1)'	System	24 Sep 2020 21:59:36

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-24T16:59:18', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'cb5e8e9d-3a4d-491a-b396-993a6b5101ae'	System	24 Sep 2020 21:59:36
User entered 'None (0)'	System	24 Sep 2020 21:59:36

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-24T16:59:20', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'cb5e8e9d-3a4d-491a-b396-993a6b5101ae'	System	24 Sep 2020 21:59:36
User entered 'None (0)'	System	24 Sep 2020 21:59:36

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-24T16:59:21', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'cb5e8e9d-3a4d-491a-b396-993a6b5101ae'	System	24 Sep 2020 21:59:36
User entered 'None (0)'	System	24 Sep 2020 21:59:36

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-24T16:59:23', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'cb5e8e9d-3a4d-491a-b396-993a6b5101ae'	System	24 Sep 2020 21:59:36
User entered 'None (0)'	System	24 Sep 2020 21:59:36

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-24T16:59:25', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'cb5e8e9d-3a4d-491a-b396-993a6b5101ae'	System	24 Sep 2020 21:59:36
User entered 'None (0)'	System	24 Sep 2020 21:59:36

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-24T16:59:29', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'cb5e8e9d-3a4d-491a-b396-993a6b5101ae'	System	24 Sep 2020 21:59:36
User entered 'No (N)'	System	24 Sep 2020 21:59:36

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-24T16:59:32', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'cb5e8e9d-3a4d-491a-b396-993a6b5101ae'	System	24 Sep 2020 21:59:36
User entered '24 Sep 2020 16:59'	System	24 Sep 2020 21:59:36

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 3'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:03:16', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'e5e6ac21-5e05-4d01-b282-a3e0af3f19b6'	System	26 Sep 2020 01:11:38
User entered 'None (0)'	System	26 Sep 2020 01:11:38

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:03:18', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'e5e6ac21-5e05-4d01-b282-a3e0af3f19b6'	System	26 Sep 2020 01:11:38
User entered 'None (0)'	System	26 Sep 2020 01:11:38

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:03:20', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'e5e6ac21-5e05-4d01-b282-a3e0af3f19b6'	System	26 Sep 2020 01:11:38
User entered 'None (0)'	System	26 Sep 2020 01:11:38

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:03:21', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'e5e6ac21-5e05-4d01-b282-a3e0af3f19b6'	System	26 Sep 2020 01:11:38
User entered 'None (0)'	System	26 Sep 2020 01:11:38

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:03:23', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'e5e6ac21-5e05-4d01-b282-a3e0af3f19b6'	System	26 Sep 2020 01:11:38
User entered 'None (0)'	System	26 Sep 2020 01:11:38

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:03:24', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'e5e6ac21-5e05-4d01-b282-a3e0af3f19b6'	System	26 Sep 2020 01:11:38
User entered 'None (0)'	System	26 Sep 2020 01:11:38

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:03:26', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'e5e6ac21-5e05-4d01-b282-a3e0af3f19b6'	System	26 Sep 2020 01:11:38
User entered 'No (N)'	System	26 Sep 2020 01:11:38

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-25T20:03:29', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'e5e6ac21-5e05-4d01-b282-a3e0af3f19b6'	System	26 Sep 2020 01:11:38
User entered '25 Sep 2020 20:03'	System	26 Sep 2020 01:11:38

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 4'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:49:42', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'd9749a04-f649-4283-84a9-69b2085456c5'	System	27 Sep 2020 00:49:56
User entered 'None (0)'	System	27 Sep 2020 00:49:56

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:49:44', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'd9749a04-f649-4283-84a9-69b2085456c5'	System	27 Sep 2020 00:49:56
User entered 'None (0)'	System	27 Sep 2020 00:49:56

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:49:45', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'd9749a04-f649-4283-84a9-69b2085456c5'	System	27 Sep 2020 00:49:56
User entered 'None (0)'	System	27 Sep 2020 00:49:56

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:49:46', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'd9749a04-f649-4283-84a9-69b2085456c5'	System	27 Sep 2020 00:49:56
User entered 'None (0)'	System	27 Sep 2020 00:49:56

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:49:48', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'd9749a04-f649-4283-84a9-69b2085456c5'	System	27 Sep 2020 00:49:56
User entered 'None (0)'	System	27 Sep 2020 00:49:56

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:49:49', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'd9749a04-f649-4283-84a9-69b2085456c5'	System	27 Sep 2020 00:49:56
User entered 'None (0)'	System	27 Sep 2020 00:49:56

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:49:51', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'd9749a04-f649-4283-84a9-69b2085456c5'	System	27 Sep 2020 00:49:56
User entered 'No (N)'	System	27 Sep 2020 00:49:56

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-26T19:49:53', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'd9749a04-f649-4283-84a9-69b2085456c5'	System	27 Sep 2020 00:49:56
User entered '26 Sep 2020 19:49'	System	27 Sep 2020 00:49:56

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 5'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:28:31', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '463c28be-78d0-48f0-b0e4-16e1fba07ead'	System	27 Sep 2020 17:28:44
User entered 'None (0)'	System	27 Sep 2020 17:28:44

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:28:32', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '463c28be-78d0-48f0-b0e4-16e1fba07ead'	System	27 Sep 2020 17:28:44
User entered 'None (0)'	System	27 Sep 2020 17:28:44

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:28:34', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '463c28be-78d0-48f0-b0e4-16e1fba07ead'	System	27 Sep 2020 17:28:44
User entered 'None (0)'	System	27 Sep 2020 17:28:44

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:28:36', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '463c28be-78d0-48f0-b0e4-16e1fba07ead'	System	27 Sep 2020 17:28:44
User entered 'None (0)'	System	27 Sep 2020 17:28:44

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:28:37', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '463c28be-78d0-48f0-b0e4-16e1fba07ead'	System	27 Sep 2020 17:28:44
User entered 'None (0)'	System	27 Sep 2020 17:28:44

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:28:38', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '463c28be-78d0-48f0-b0e4-16e1fba07ead'	System	27 Sep 2020 17:28:44
User entered 'None (0)'	System	27 Sep 2020 17:28:44

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:28:40', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '463c28be-78d0-48f0-b0e4-16e1fba07ead'	System	27 Sep 2020 17:28:44
User entered 'No (N)'	System	27 Sep 2020 17:28:44

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-27T12:28:42', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '463c28be-78d0-48f0-b0e4-16e1fba07ead'	System	27 Sep 2020 17:28:44
User entered '27 Sep 2020 12:28'	System	27 Sep 2020 17:28:44

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 6'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T15:56:34', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4a903eed-36cc-454a-ab16-9b64a91217c0'	System	28 Sep 2020 20:56:49
User entered 'None (0)'	System	28 Sep 2020 20:56:49

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T15:56:35', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4a903eed-36cc-454a-ab16-9b64a91217c0'	System	28 Sep 2020 20:56:49
User entered 'None (0)'	System	28 Sep 2020 20:56:49

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T15:56:37', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4a903eed-36cc-454a-ab16-9b64a91217c0'	System	28 Sep 2020 20:56:49
User entered 'None (0)'	System	28 Sep 2020 20:56:49

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T15:56:39', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4a903eed-36cc-454a-ab16-9b64a91217c0'	System	28 Sep 2020 20:56:49
User entered 'None (0)'	System	28 Sep 2020 20:56:49

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T15:56:40', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4a903eed-36cc-454a-ab16-9b64a91217c0'	System	28 Sep 2020 20:56:49
User entered 'None (0)'	System	28 Sep 2020 20:56:49

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T15:56:42', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4a903eed-36cc-454a-ab16-9b64a91217c0'	System	28 Sep 2020 20:56:49
User entered 'None (0)'	System	28 Sep 2020 20:56:49

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T15:56:44', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4a903eed-36cc-454a-ab16-9b64a91217c0'	System	28 Sep 2020 20:56:49
User entered 'No (N)'	System	28 Sep 2020 20:56:49

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-28T15:56:46', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4a903eed-36cc-454a-ab16-9b64a91217c0'	System	28 Sep 2020 20:56:49
User entered '28 Sep 2020 15:56'	System	28 Sep 2020 20:56:49

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	23 Sep 2020 15:48:52
User entered 'Day 7'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:03:28', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3bbc4cd0-fc24-479b-be11-3c06c21058f7'	System	29 Sep 2020 17:04:08
User entered 'No interference with activity (1)'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:03:31', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3bbc4cd0-fc24-479b-be11-3c06c21058f7'	System	29 Sep 2020 17:04:08
User entered 'None (0)'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:03:46', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3bbc4cd0-fc24-479b-be11-3c06c21058f7'	System	29 Sep 2020 17:04:08
User entered 'None (0)'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:03:48', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3bbc4cd0-fc24-479b-be11-3c06c21058f7'	System	29 Sep 2020 17:04:08
User entered 'No interference with activity (1)'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:03:50', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3bbc4cd0-fc24-479b-be11-3c06c21058f7'	System	29 Sep 2020 17:04:08
User entered 'None (0)'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:03:54', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3bbc4cd0-fc24-479b-be11-3c06c21058f7'	System	29 Sep 2020 17:04:08
User entered 'None (0)'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:03:57', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3bbc4cd0-fc24-479b-be11-3c06c21058f7'	System	29 Sep 2020 17:04:08
User entered 'No (N)'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-29T12:04:04', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3bbc4cd0-fc24-479b-be11-3c06c21058f7'	System	29 Sep 2020 17:04:08
User entered '29 Sep 2020 12:04'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 15:48:52

US3492242

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	29 Sep 2020 17:04:08
User entered 'Day 8'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-30T12:01:16', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'df101a9a-05d4-4d0f-b531-d1593b199bd9'	System	30 Sep 2020 17:01:51
User entered 'No interference with activity (1)'	System	30 Sep 2020 17:01:51

US3492242

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-30T12:01:21', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'df101a9a-05d4-4d0f-b531-d1593b199bd9'	System	30 Sep 2020 17:01:51
User entered '30 Sep 2020 12:01'	System	30 Sep 2020 17:01:51

US3492242

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	29 Sep 2020 17:04:08
User entered 'Day 9'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:45:27

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 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-10-01T23:59:55', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'fc9cd63d-6153-4d63-94e7-89dcd0b174a7'	System	02 Oct 2020 05:00:01
User entered 'None (0)'	System	02 Oct 2020 05:00:01

US3492242

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:45:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-10-01T23:59:57', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'fc9cd63d-6153-4d63-94e7-89dcd0b174a7'	System	02 Oct 2020 05:00:01
User entered '01 Oct 2020 23:59'	System	02 Oct 2020 05:00:01

US3492242

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	29 Sep 2020 17:04:08
User entered 'Day 8'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:45:27

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-30T12:01:26', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '707fa925-a532-472a-a7e2-db14ae9aeb84'	System	30 Sep 2020 17:02:03
User entered 'None (0)'	System	30 Sep 2020 17:02:03

US3492242

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:45:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-30T12:01:30', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '707fa925-a532-472a-a7e2-db14ae9aeb84'	System	30 Sep 2020 17:02:03
User entered '30 Sep 2020 12:01'	System	30 Sep 2020 17:02:03

US3492242

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
Data entry locked.	System	29 Sep 2020 17:04:08
User entered 'Day 8'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-30T12:01:35', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '0af17067-2f7b-4fde-a5f5-f080ba53fb87'	System	30 Sep 2020 17:02:13
User entered 'No (N)'	System	30 Sep 2020 17:02:13

US3492242

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:45:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-09-30T12:01:38', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '0af17067-2f7b-4fde-a5f5-f080ba53fb87'	System	30 Sep 2020 17:02:13
User entered '30 Sep 2020 12:01'	System	30 Sep 2020 17:02:13

US3492242

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:45:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 17:04:08

US3492242

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:45:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:45
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 17:04:08

US3492242

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	Addis Mekonnen (b) (4)	30 Sep 2020 19:56:31

US3492242

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '30 Sep 2020'	Addis Mekonnen (b) (4)	30 Sep 2020 19:56:31

US3492242

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Contact Made (CONTACT MADE)'	Addis Mekonnen (b) (4)	30 Sep 2020 19:56:31

US3492242

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Addis Mekonnen (b) (4)	30 Sep 2020 19:56:31

US3492242

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	Addis Mekonnen (b) (4)	30 Sep 2020 19:56:40

US3492242

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'I'	System	30 Sep 2020 19:56:40

US3492242

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	12 Nov 2020 14:45:10
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	12 Nov 2020 00:08:20
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 00:08:20

US3492242

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:08:20

US3492242

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty; reason for change Per Query Resolution	(b) (4)	12 Nov 2020 14:45:10
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lorna Sanchez McCann (b) (4), (b) (6)	12 Nov 2020 00:08:20

US3492242

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'in illness visit phase'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:08:20

US3492242

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:08:39

US3492242

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'I'	System	12 Nov 2020 00:08:39

US3492242

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	12 Nov 2020 14:44:55
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	12 Nov 2020 00:08:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 00:08:58

US3492242

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:08:58

US3492242

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty; reason for change Per Query Resolution	(b) (4)	12 Nov 2020 14:44:55
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lorna Sanchez McCann (b) (4)	12 Nov 2020 00:08:58
	(b) (4), (b) (6)	

US3492242

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'IN ILLNESS VISIT PHASE'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:08:58

US3492242

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:09:36

US3492242

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'I'	System	12 Nov 2020 00:09:36

US3492242

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:09:50

US3492242

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:09:50

US3492242

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:09:50

US3492242

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'VISIT2'	System	12 Nov 2020 00:09:50

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:10:54

US3492242

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:44

US3492242

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:44

US3492242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:24

US3492242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Confirmed COVID-19 (COVID)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:24

US3492242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:24

US3492242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:10:24

US3492242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:24

US3492242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:24

US3492242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:10:24

US3492242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:24

US3492242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:10:24

US3492242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:10:24

US3492242

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:34

US3492242

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:34

US3492242

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:10:34

US3492242

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:10:34

US3492242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:04

US3492242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:45:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	12 Nov 2020 00:11:04

US3492242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:45:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:04

US3492242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:45:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:04

US3492242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:45:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:11:04

US3492242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:45:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	12 Nov 2020 00:11:04

US3492242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:45:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:04

US3492242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:45:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:04

US3492242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:45:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	12 Nov 2020 00:11:04

US3492242

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:10

US3492242

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered '1'	System	12 Nov 2020 00:11:10

US3492242

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	12 Nov 2020 14:44:40
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	12 Nov 2020 00:11:22
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 00:11:22

US3492242

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:22

US3492242

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty; reason for change Per Query Resolution	(b) (4)	12 Nov 2020 14:44:40
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lorna Sanchez McCann (b) (4), (b) (6)	12 Nov 2020 00:11:22

US3492242

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'IN ILLNESS VISIT PHASE'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:22

US3492242

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:28

US3492242

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'I'	System	12 Nov 2020 00:11:28

US3492242

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	12 Nov 2020 14:44:25
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	12 Nov 2020 00:11:37
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 00:11:37

US3492242

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:37

US3492242

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty; reason for change Per Query Resolution	(b) (4)	12 Nov 2020 14:44:25
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lorna Sanchez McCann (b) (4), (b) (6)	12 Nov 2020 00:11:37

US3492242

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'IN ILLNESS VISIT PHASE'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:37

US3492242

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:43

US3492242

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'I'	System	12 Nov 2020 00:11:43

US3492242

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:57

US3492242

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:57

US3492242

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:57

US3492242

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:57

US3492242

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:12:11

US3492242

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'I'	System	12 Nov 2020 00:12:11

US3492242

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	20 Dec 2020 18:35:53

US3492242

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:35:53

US3492242

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	20 Dec 2020 18:35:53

US3492242

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'VISIT3'	System	20 Dec 2020 18:35:53

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	20 Dec 2020 18:36:07

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:36:07

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:36:07

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	20 Dec 2020 18:36:07

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:36:07

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:36:07

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	20 Dec 2020 18:36:07

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:36:07

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	20 Dec 2020 18:36:07

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:36:07

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	20 Dec 2020 18:36:07

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	20 Dec 2020 18:36:07

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	20 Dec 2020 18:36:07

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:36:07

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	20 Dec 2020 18:36:07

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22

US3492242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22

US3492242

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	20 Dec 2020 18:36:14

US3492242

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:36:14

US3492242

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	20 Dec 2020 18:36:21

US3492242

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:36:21

US3492242

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:36:21

US3492242

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered empty.	System	20 Dec 2020 18:36:21

US3492242

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	16 Dec 2020 17:33:27

US3492242

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered '1'	System	16 Dec 2020 17:33:27

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 10:58:48
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'no AE, routine f/u for HTN' (Site from DM).	Andrea Wendrow (b) (4)	20 Dec 2020 18:37:55
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Dec 2020 10:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-11-24T02:52:13', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '593c743c-aa33-4b93-9269-492a50141e01'	System	24 Nov 2020 08:53:07
User entered 'Yes (Y)'	System	24 Nov 2020 08:53:07

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-11-24T02:52:29', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '593c743c-aa33-4b93-9269-492a50141e01'	System	24 Nov 2020 08:53:07
User entered 'No (N)'	System	24 Nov 2020 08:53:07

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[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 (787b294b4371ac36)', Time: '2020-11-24T02:52:36', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '593c743c-aa33-4b93-9269-492a50141e01'	System	24 Nov 2020 08:53:07
User entered 'No (N)'	System	24 Nov 2020 08:53:07

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[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 (787b294b4371ac36)', Time: '2020-11-24T02:52:44', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '593c743c-aa33-4b93-9269-492a50141e01'	System	24 Nov 2020 08:53:07
User entered 'Yes (Y)'	System	24 Nov 2020 08:53:07

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-11-24T02:52:49', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '593c743c-aa33-4b93-9269-492a50141e01'	System	24 Nov 2020 08:53:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Nov 2020 08:53:07

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-11-24T02:52:53', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '593c743c-aa33-4b93-9269-492a50141e01'	System	24 Nov 2020 08:53:07
User entered '24 Nov 2020 02:52:53'	System	24 Nov 2020 08:53:07

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-12-14T01:43:44', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'a1fd248e-2e1c-4682-a772-3ddfaeb04bb9'	System	14 Dec 2020 07:43:58
User entered 'No (N)'	System	14 Dec 2020 07:43:58

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-12-14T01:43:50', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'a1fd248e-2e1c-4682-a772-3ddfaeb04bb9'	System	14 Dec 2020 07:43:58
User entered 'No (N)'	System	14 Dec 2020 07:43:58

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-12-14T01:43:54', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'a1fd248e-2e1c-4682-a772-3ddfaeb04bb9' User entered '14 Dec 2020 01:43:54'	System	14 Dec 2020 07:43:58
	System	14 Dec 2020 07:43:58

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-12-18T00:08:20', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '5b03c879-4877-4095-9fe3-cbd47d373a48'	System	18 Dec 2020 06:08:37
User entered 'No (N)'	System	18 Dec 2020 06:08:37

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-12-18T00:08:26', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '5b03c879-4877-4095-9fe3-cbd47d373a48'	System	18 Dec 2020 06:08:37
User entered 'No (N)'	System	18 Dec 2020 06:08:37

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2020-12-18T00:08:30', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '5b03c879-4877-4095-9fe3-cbd47d373a48'	System	18 Dec 2020 06:08:37
User entered '18 Dec 2020 00:08:30'	System	18 Dec 2020 06:08:37

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-01-09T17:50:47', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3548cce6-7c42-4523-bc52-eb124752d1cb'	System	09 Jan 2021 23:50:59
User entered 'No (N)'	System	09 Jan 2021 23:50:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-01-09T17:50:54', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3548cce6-7c42-4523-bc52-eb124752d1cb'	System	09 Jan 2021 23:50:59
User entered 'No (N)'	System	09 Jan 2021 23:50:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-01-09T17:50:57', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3548cce6-7c42-4523-bc52-eb124752d1cb' User entered '09 Jan 2021 17:50:57'	System	09 Jan 2021 23:50:59
	System	09 Jan 2021 23:50:59

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-01-17T11:12:41', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '45892ccf-a0a0-42f3-84a4-e1a1b61ce709'	System	17 Jan 2021 17:13:05
User entered 'No (N)'	System	17 Jan 2021 17:13:05

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-01-17T11:13:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '45892ccf-a0a0-42f3-84a4-e1a1b61ce709'	System	17 Jan 2021 17:13:05
User entered 'No (N)'	System	17 Jan 2021 17:13:05

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-01-17T11:13:03', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '45892ccf-a0a0-42f3-84a4-e1a1b61ce709'	System	17 Jan 2021 17:13:05
User entered '17 Jan 2021 11:13:03'	System	17 Jan 2021 17:13:05

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-01-22T00:02:54', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '24d6948a-77b1-47dd-97d8-4b21c6d00688'	System	22 Jan 2021 06:03:02
User entered 'No (N)'	System	22 Jan 2021 06:03:02

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-01-22T00:02:56', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '24d6948a-77b1-47dd-97d8-4b21c6d00688'	System	22 Jan 2021 06:03:02
User entered 'No (N)'	System	22 Jan 2021 06:03:02

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-01-22T00:02:58', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '24d6948a-77b1-47dd-97d8-4b21c6d00688'	System	22 Jan 2021 06:03:02
User entered '22 Jan 2021 00:02:58'	System	22 Jan 2021 06:03:02

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-02-01T17:59:46', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '586ec70f-9e34-45da-b7bb-f61dbf02b9aa'	System	01 Feb 2021 23:59:57
User entered 'No (N)'	System	01 Feb 2021 23:59:57

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-02-01T17:59:51', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '586ec70f-9e34-45da-b7bb-f61dbf02b9aa'	System	01 Feb 2021 23:59:57
User entered 'No (N)'	System	01 Feb 2021 23:59:57

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-02-01T17:59:54', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '586ec70f-9e34-45da-b7bb-f61dbf02b9aa'	System	01 Feb 2021 23:59:57
User entered '01 Feb 2021 17:59:54'	System	01 Feb 2021 23:59:57

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-02-05T00:12:49', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '392d967c-99b9-4e01-a121-54f2a80ab58a'	System	05 Feb 2021 06:13:12
User entered 'Yes (Y)'	System	05 Feb 2021 06:13:12

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-02-05T00:12:53', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '392d967c-99b9-4e01-a121-54f2a80ab58a'	System	05 Feb 2021 06:13:12
User entered 'No (N)'	System	05 Feb 2021 06:13:12

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[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 (787b294b4371ac36)', Time: '2021-02-05T00:12:59', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '392d967c-99b9-4e01-a121-54f2a80ab58a'	System	05 Feb 2021 06:13:12
User entered 'No (N)'	System	05 Feb 2021 06:13:12

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[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 (787b294b4371ac36)', Time: '2021-02-05T00:13:06', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '392d967c-99b9-4e01-a121-54f2a80ab58a'	System	05 Feb 2021 06:13:12
User entered 'No (N)'	System	05 Feb 2021 06:13:12

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-02-05T00:13:10', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '392d967c-99b9-4e01-a121-54f2a80ab58a'	System	05 Feb 2021 06:13:12
User entered '05 Feb 2021 00:13:10'	System	05 Feb 2021 06:13:12

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-02-12T00:14:01', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'c4660c79-3ba4-436a-8001-9ef0f169a0d7'	System	12 Feb 2021 06:14:09
User entered 'No (N)'	System	12 Feb 2021 06:14:09

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-02-12T00:14:03', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'c4660c79-3ba4-436a-8001-9ef0f169a0d7'	System	12 Feb 2021 06:14:09
User entered 'No (N)'	System	12 Feb 2021 06:14:09

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-02-12T00:14:05', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'c4660c79-3ba4-436a-8001-9ef0f169a0d7'	System	12 Feb 2021 06:14:09
User entered '12 Feb 2021 00:14:05'	System	12 Feb 2021 06:14:09

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-02-19T01:53:54', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3abb2a22-e9da-42dc-91cb-dd3cf243edac'	System	19 Feb 2021 07:54:06
User entered 'No (N)'	System	19 Feb 2021 07:54:06

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-02-19T01:53:57', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3abb2a22-e9da-42dc-91cb-dd3cf243edac'	System	19 Feb 2021 07:54:06
User entered 'No (N)'	System	19 Feb 2021 07:54:06

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-02-19T01:54:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '3abb2a22-e9da-42dc-91cb-dd3cf243edac'	System	19 Feb 2021 07:54:06
User entered '19 Feb 2021 01:54:00'	System	19 Feb 2021 07:54:06

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-02-26T01:23:44-06:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '25ee1a2c-834b-4bdd-ad8f-4b52a85a50a4'	System	26 Feb 2021 07:23:53
User entered 'No (N)'	System	26 Feb 2021 07:23:53

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-02-26T01:23:47-06:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '25ee1a2c-834b-4bdd-ad8f-4b52a85a50a4'	System	26 Feb 2021 07:23:53
User entered 'No (N)'	System	26 Feb 2021 07:23:53

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-02-26T01:23:49-06:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '25ee1a2c-834b-4bdd-ad8f-4b52a85a50a4' User entered '26 Feb 2021 01:23:49'	System	26 Feb 2021 07:23:53
	System	26 Feb 2021 07:23:53

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-03-07T12:29:02-06:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '2fd7a3f9-f1ad-4c31-888f-f391e15f94f3'	System	07 Mar 2021 18:29:12
User entered 'No (N)'	System	07 Mar 2021 18:29:12

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-03-07T12:29:06-06:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '2fd7a3f9-f1ad-4c31-888f-f391e15f94f3'	System	07 Mar 2021 18:29:12
User entered 'No (N)'	System	07 Mar 2021 18:29:12

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-03-07T12:29:08-06:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '2fd7a3f9-f1ad-4c31-888f-f391e15f94f3'	System	07 Mar 2021 18:29:12
User entered '07 Mar 2021 12:29:08'	System	07 Mar 2021 18:29:12

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-03-12T00:02:43-06:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'b1b395f9-ec94-4823-b73e-69b9de5790da'	System	12 Mar 2021 06:02:51
User entered 'No (N)'	System	12 Mar 2021 06:02:51

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-03-12T00:02:45-06:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'b1b395f9-ec94-4823-b73e-69b9de5790da'	System	12 Mar 2021 06:02:51
User entered 'No (N)'	System	12 Mar 2021 06:02:51

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-03-12T00:02:47-06:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'b1b395f9-ec94-4823-b73e-69b9de5790da' User entered '12 Mar 2021 00:02:47'	System	12 Mar 2021 06:02:51
	System	12 Mar 2021 06:02:51

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-03-19T00:29:47-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '1f90b8bc-a8a5-4151-bf02-dc6d4bd0e382'	System	19 Mar 2021 05:29:57
User entered 'No (N)'	System	19 Mar 2021 05:29:57

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-03-19T00:29:50-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '1f90b8bc-a8a5-4151-bf02-dc6d4bd0e382'	System	19 Mar 2021 05:29:57
User entered 'No (N)'	System	19 Mar 2021 05:29:57

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-03-19T00:29:53-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '1f90b8bc-a8a5-4151-bf02-dc6d4bd0e382' User entered '19 Mar 2021 00:29:53'	System	19 Mar 2021 05:29:57
	System	19 Mar 2021 05:29:57

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-03-29T01:10:25-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'ea914619-a920-43d8-8000-fb5005deacba' User entered 'No (N)'	System	29 Mar 2021 06:10:35
	System	29 Mar 2021 06:10:35

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-03-29T01:10:29-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'ea914619-a920-43d8-8000-fb5005deacba' User entered 'No (N)'	System	29 Mar 2021 06:10:35
	System	29 Mar 2021 06:10:35

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-03-29T01:10:31-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'ea914619-a920-43d8-8000-fb5005deacba' User entered '29 Mar 2021 01:10:31'	System	29 Mar 2021 06:10:35
	System	29 Mar 2021 06:10:35

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-04-02T09:27:10-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'fc4ca1ea-ffb1-4f41-b39c-24856e3846b9'	System	02 Apr 2021 14:27:21
User entered 'No (N)'	System	02 Apr 2021 14:27:21

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-04-02T09:27:14-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'fc4ca1ea-ffb1-4f41-b39c-24856e3846b9'	System	02 Apr 2021 14:27:21
User entered 'No (N)'	System	02 Apr 2021 14:27:21

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-04-02T09:27:16-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: 'fc4ca1ea-ffb1-4f41-b39c-24856e3846b9'	System	02 Apr 2021 14:27:21
User entered '02 Apr 2021 09:27:16'	System	02 Apr 2021 14:27:21

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-04-09T00:09:02-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4bbbc3c6-b330-4126-875d-4b9244c3ab61'	System	09 Apr 2021 05:09:14
User entered 'No (N)'	System	09 Apr 2021 05:09:14

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-04-09T00:09:09-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4bbbc3c6-b330-4126-875d-4b9244c3ab61'	System	09 Apr 2021 05:09:14
User entered 'No (N)'	System	09 Apr 2021 05:09:14

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-04-09T00:09:11-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '4bbbc3c6-b330-4126-875d-4b9244c3ab61'	System	09 Apr 2021 05:09:14
User entered '09 Apr 2021 00:09:11'	System	09 Apr 2021 05:09:14

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-04-24T19:37:31-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '9905e76e-194d-45f8-bb86-332ed2ad2990'	System	25 Apr 2021 00:37:39
User entered 'No (N)'	System	25 Apr 2021 00:37:39

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-04-24T19:37:34-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '9905e76e-194d-45f8-bb86-332ed2ad2990'	System	25 Apr 2021 00:37:39
User entered 'No (N)'	System	25 Apr 2021 00:37:39

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-04-24T19:37:36-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '9905e76e-194d-45f8-bb86-332ed2ad2990'	System	25 Apr 2021 00:37:39
User entered '24 Apr 2021 19:37:36'	System	25 Apr 2021 00:37:39

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-05-01T01:31:59-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '700d82f4-5e0a-4e49-906a-252276e965e7'	System	01 May 2021 06:32:08
User entered 'No (N)'	System	01 May 2021 06:32:08

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-05-01T01:32:02-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '700d82f4-5e0a-4e49-906a-252276e965e7'	System	01 May 2021 06:32:08
User entered 'No (N)'	System	01 May 2021 06:32:08

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-05-01T01:32:03-05:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '700d82f4-5e0a-4e49-906a-252276e965e7'	System	01 May 2021 06:32:08
User entered '01 May 2021 01:32:03'	System	01 May 2021 06:32:08

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:23:04

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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 10:23:04
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 10:23:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 10:23:04

US3492242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:45:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:04
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 10:23:04

US3492242

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:45:27

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-03-07T12:28:24-06:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '22f6d258-b12f-46be-814f-8916de687ef8'	System	07 Mar 2021 18:28:57
User entered 'No (N)'	System	07 Mar 2021 18:28:57

US3492242

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:45:27

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (787b294b4371ac36)', Time: '2021-03-07T12:28:52-06:00', User OID: 'PatientReportedOutcome (US3492242)', ODM File OID: '22f6d258-b12f-46be-814f-8916de687ef8'	System	07 Mar 2021 18:28:57
User entered '07 Mar 2021 12:28:52'	System	07 Mar 2021 18:28:57

US3492242

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	18 Dec 2020 19:19:53

US3492242

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '18 Dec 2020'	Nia Moragne-O'Neal (b) (4)	18 Dec 2020 19:19:53

US3492242

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	18 Dec 2020 19:19:53

US3492242

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Nia Moragne-O'Neal (b) (4)	18 Dec 2020 19:19:53

US3492242

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	18 Dec 2020 19:19:56

US3492242

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:49:22
User entered 'I'	System	18 Dec 2020 19:19:56

US3492242

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:43

US3492242

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:43

US3492242

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:43

US3492242

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:43

US3492242

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:51

US3492242

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User entered 'I'	System	21 Jan 2021 17:36:51

US3492242

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:04:07

US3492242

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:04:07

US3492242

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:04:07

US3492242

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:04:07

US3492242

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:04:25

US3492242

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User entered 'I'	System	11 Mar 2021 16:04:25

US3492242

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Yes (Y)'	Ian Feather (b) (4)	17 Mar 2021 13:39:56

US3492242

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '17 Mar 2021'	Ian Feather (b) (4)	17 Mar 2021 13:39:56

US3492242

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Contact Made (CONTACT MADE)'	Ian Feather (b) (4)	17 Mar 2021 13:39:56

US3492242

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered empty.	Ian Feather (b) (4)	17 Mar 2021 13:39:56

US3492242

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Yes (Y)'	Ian Feather (b) (4)	17 Mar 2021 13:40:04

US3492242

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:05
User entered 'I'	System	17 Mar 2021 13:40:04

US3492242

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:23:58

US3492242

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '30 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:23:58

US3492242

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:23:58

US3492242

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Apr 2021 17:23:58

US3492242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:24:36

US3492242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '30 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:24:36

US3492242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '11:52'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:24:36

US3492242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
User entered '30 Apr 2021 11:52'	System	30 Apr 2021 17:24:36

US3492242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:24:36

US3492242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:24:36

US3492242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:24:36

US3492242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '63'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:24:36

US3492242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Apr 2021 17:24:36

US3492242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '16'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:24:36

US3492242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Apr 2021 17:24:36

US3492242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '186'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:24:36

US3492242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Apr 2021 17:24:36

US3492242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '97'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:24:36

US3492242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Apr 2021 17:24:36

US3492242

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:24:45

US3492242

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:24:45

US3492242

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:25:04

US3492242

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '30 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:25:04

US3492242

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '12:17'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:25:04

US3492242

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Apr 2021 12:17'	System	30 Apr 2021 17:25:04

US3492242

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:25:24

US3492242

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 17:25:24

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:45:27

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:54:38
User entered '3 Oct 2020'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:15:06

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:45:27

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:54:38
User entered '09:00'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:15:06

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:45:27

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:59
User entered '3 Oct 2020 09:00'	System	03 Oct 2020 20:15:06

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:45:27

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:54:38
User entered 'Safety Call (Safety Call)'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:15:06

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:45:27

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:40:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:54:38
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:15:06

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 2 (Day 2)'	Richard Novak (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '29 Sep 2020'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:42:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query ' Per CDM: Assessment Not Done is checked yet data is present. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 11:29:38
Query ' Per CDM: Assessment Not Done is checked yet data is present. Please review and reconcile.' answered with '-----Corrected. Thank you.-----' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 21:00:46
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 21:00:27
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 21:00:27
User opened query ' Per CDM: Assessment Not Done is checked yet data is present. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '1'	Richard Novak (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	05 Nov 2020 22:42:39
User entered empty.	System	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:00
	(b) (4)	

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:00
	(b) (4)	

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:42:39
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:00

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 3 (Day 3)'	Richard Novak (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '30 Sep 2020'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered '1'	(b) (4) Richard Novak (b) (4)	05 Oct 2020 01:18:20
	(b) (4)	

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	05 Nov 2020 22:43:48
User entered empty.	System	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:20

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:43:48
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:20

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 03 Oct 2020 symptom log on log line 4. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 15:42:05
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 03 Oct 2020 symptom log on log line 4. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'updated' (Site from DM).	Andrea Wendrow (b) (4)	20 Apr 2021 15:06:23
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 03 Oct 2020 symptom log on log line 4. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:29:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 4 (Day 4)'	Richard Novak (b) (4)	05 Oct 2020 01:18:37

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '1 Oct 2020'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:37

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered '1'	(b) (4) Richard Novak (b) (4)	05 Oct 2020 01:18:37
	(b) (4)	

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:37

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	05 Nov 2020 22:44:45
User entered empty.	System	05 Oct 2020 01:18:37

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:37

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:37

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:37

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:37

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:37

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:37

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:37

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:37

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:37

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:37

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:37

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:37

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:37

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:37

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:07:53
DataPoint Un-verified.	Andrea Wendrow (b) (4)	20 Apr 2021 15:05:46
Signature has been broken.	(b) (4) Andrea Wendrow (b) (4)	20 Apr 2021 15:05:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Andrea Wendrow (b) (4)	20 Apr 2021 15:05:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:37

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:07:53
DataPoint Un-verified.	Andrea Wendrow (b) (4)	20 Apr 2021 15:05:46
Signature has been broken.	(b) (4) Andrea Wendrow (b) (4)	20 Apr 2021 15:05:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Andrea Wendrow (b) (4)	20 Apr 2021 15:05:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:37

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:44:45
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:37

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 5 (Day 5)'	Richard Novak (b) (4)	05 Oct 2020 01:18:51

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '2 Oct 2020'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:51

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0' reason for change: New Information	Andrea Wendrow (b) (4)	05 Nov 2020 22:47:09
User entered '1'	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:51

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:51

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	05 Nov 2020 22:46:16
User entered empty.	System	05 Oct 2020 01:18:51

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:51

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:51

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:51

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:51

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:51

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:51

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:51

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:51

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:51

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:51

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:51

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:51

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:51

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:51

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:18:51

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:51

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Nov 2020 22:46:16
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:18:51

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 6 (Day 6)'	Richard Novak (b) (4)	05 Oct 2020 01:21:43

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '3 Oct 2020'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:42:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query 'Per CDM: It appears that O2 saturation was not provided for days 6 and 7. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 11:30:00
Query 'Per CDM: It appears that O2 saturation was not provided for days 6 and 7. If not collected, please consider recording as Not Done.' answered with '-----Corrected. Thank You.-----' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 21:04:08
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 21:01:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 21:01:42
User opened query 'Per CDM: It appears that O2 saturation was not provided for days 6 and 7. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 15:26:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	20 Jan 2021 21:01:42
User entered empty.	System	05 Oct 2020 01:21:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98.8' F reason for change: New Information	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:29:50
User entered empty.	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Moderate (Moderate)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Moderate (Moderate)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Moderate (Moderate)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:29:50
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Moderate (Moderate)' reason for change: New Information	Richard Novak (b) (4)	05 Oct 2020 01:29:50
User entered 'None (None)'	(b) (4) Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:21:43

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 7 (Day 7)'	Richard Novak (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '4 Oct 2020'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:42:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query 'Per CDM: It appears that O2 saturation was not provided. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 13:21:23
Query 'Per CDM: It appears that O2 saturation was not provided. If not collected, please consider recording as Not Done.' answered with '-----Corrected. Thank You.-----' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 16:08:42
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 16:08:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 16:08:27
User opened query 'Per CDM: It appears that O2 saturation was not provided. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 11:31:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Richard Novak (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	21 Jan 2021 16:08:27
User entered empty.	System	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98.1' F	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Moderate (Moderate)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Moderate (Moderate)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Moderate (Moderate)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Moderate (Moderate)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	05 Oct 2020 01:28:25

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 8 (Day 8)'	(b) (4) Diana Bahena (b) (4)	05 Oct 2020 21:53:05
	(b) (4)	

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '05 Oct 2020'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '99'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	05 Oct 2020 21:53:05

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '99.1' F	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Diana Bahena (b) (4)	05 Oct 2020 21:53:32
User entered empty.	(b) (4) Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:53:05

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 9 (Day 9)'	(b) (4) Diana Bahena (b) (4)	06 Oct 2020 20:04:09
	(b) (4)	

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '06 Oct 2020'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98.6' F	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	06 Oct 2020 20:04:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 10 (Day 10)'	(b) (4) Andrea Wendrow (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '7 Oct 2020'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '97'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '97.9' F	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:07:18

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 11 (Day 11)'	(b) (4) Andrea Wendrow (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '8 Oct 2020'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98.2' F	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Not Done (Not Done)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:17:43

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 12 (Day 12)'	(b) (4) Diana Bahena (b) (4)	12 Oct 2020 19:52:17

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '09 Oct 2020'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	12 Oct 2020 19:52:17

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98.1' F	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:52:17

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 13 (Day 13)'	(b) (4) Diana Bahena (b) (4)	12 Oct 2020 19:53:38
	(b) (4)	

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '10 Oct 2020'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	12 Oct 2020 19:53:38

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98.5' F	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 14 (Day 14)'	(b) (4) Diana Bahena (b) (4)	12 Oct 2020 19:54:12
	(b) (4)	

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '11 Oct 2020'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'I'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered empty.	System	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered empty.	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:54:12

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 15 (Day 15)'	Diana Bahena (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '12 Oct 2020'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98.3' F	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 19:55:27

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 16 (Day 16)'	Diana Bahena (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '13 Oct 2020' reason for change: Data Entry Error	Diana Bahena (b) (4)	14 Oct 2020 15:09:50
User entered '12 Oct 2020'	(b) (4) Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98.5' F	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:54:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 17 (Day 17)'	Diana Bahena (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '14 Oct 2020'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98.4' F	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 15:11:39

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 18 (Day 18)'	(b) (4) Diana Bahena (b) (4)	15 Oct 2020 19:50:53
	(b) (4)	

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '15 Oct 2020'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	15 Oct 2020 19:50:53

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98.2' F	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	15 Oct 2020 19:50:53

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 19 (Day 19)'	Diana Bahena (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '16 Oct 2020'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98.6' F	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	16 Oct 2020 21:29:36

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 20 (Day 20)'	Diana Bahena (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '17 Oct 2020'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98.7' F	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:53:38

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 21 (Day 21)'	Diana Bahena (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '18 Oct 2020'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98.5' F	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	19 Oct 2020 13:56:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 22 (Day 22)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '19 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98.4' F	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 15:18:22

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 23 (Day 23)'	Diana Bahena (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '20 Oct 2020'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '97.9' F	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 19:35:31

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Day 24 (Day 24)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query 'Per CDM: it appears there may be some additional records missing as there is a Saliva collection with date of 25OCT2020 however symptoms stop at date of 21OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 11:44:04
Query 'Per CDM: it appears there may be some additional records missing as there is a Saliva collection with date of 25OCT2020 however symptoms stop at date of 21OCT2020. Please reconcile or clarify.' answered with 'this is correct' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	11 Nov 2020 04:03:29
User opened query 'Per CDM: it appears there may be some additional records missing as there is a Saliva collection with date of 25OCT2020 however symptoms stop at date of 21OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:46:47
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User entered '%'	System	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered '98.5' F	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:45:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:44:11

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:27

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:11
User entered '05 Oct 2020' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	09 Oct 2020 18:24:10
User entered '01 Oct 2020'	(b) (4) Andrea Wendrow (b) (4)	03 Oct 2020 20:16:15
	(b) (4)	

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Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:27

[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 03:43:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:11
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:16:15

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:27

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 03:43:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:11
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 12:15:29
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)	03 Oct 2020 20:16:27
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	03 Oct 2020 20:16:15
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	03 Oct 2020 20:16:15

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Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:27

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:11
User entered '05 Oct 2020' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	09 Oct 2020 18:24:10
User entered '1 Oct 2020'	(b) (4) Andrea Wendrow (b) (4)	03 Oct 2020 20:16:15
	(b) (4)	

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Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:27

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:11
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:16:15

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Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:27

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:11
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:16:15

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Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:27

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:11
User entered 'No (N)' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	09 Oct 2020 18:24:10
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	03 Oct 2020 20:16:15

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:27

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:11
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 18:24:10
User entered 'Chicago Department of Public Health COVID-19 testing center'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:16:15

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Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:27

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:11
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	09 Oct 2020 18:24:10
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	03 Oct 2020 20:16:15
	(b) (4)	

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Folder: Covid-19 Assessment 03 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:45:27

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:36
User entered 'I'	System	03 Oct 2020 20:16:15

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Generated On: 11 Aug 2021 22:45:27

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered 'No (N)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

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 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 21:54:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Oct 2020 21:54:16
User entered 'No (N)' reason for change: Data Entry Error	Diana Bahena (b) (4)	05 Oct 2020 21:54:16
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	05 Oct 2020 21:54:09
	Diana Bahena (b) (4)	05 Oct 2020 21:54:09
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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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 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:17:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 18:17:56
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 18:17:56
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 21:54:09
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:17:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 18:17:56
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 18:17:56
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 21:54:09
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Folder: Covid-19 Assessment 03 Oct 2020

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Generated On: 11 Aug 2021 22:45:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Generated On: 11 Aug 2021 22:45:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered 'No (N)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:18:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 18:18:16
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 18:18:16
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 21:54:09
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Folder: Covid-19 Assessment 03 Oct 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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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 03:43:50
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 16:18:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
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) (4), (b) (6)	20 Jan 2021 20:47:59
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 22:44:27
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered 'No (N)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:47:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 20:47:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:54:09

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:47:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 20:47:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:47:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 20:47:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:47:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 20:47:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered 'No (N)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:47:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 20:47:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[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 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered 'No (N)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

US3492242

Folder: Covid-19 Assessment 03 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:45:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:54:09

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Folder: Covid-19 Assessment 03 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:45:27

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:43:58
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:42:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 20:56:24

US3492242

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:45:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Andrea Wendrow (b) (4)	09 Oct 2020 18:30:34

US3492242

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:45:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:40
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 18:30:34

US3492242

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:45:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:40
User entered '7 Oct 2020'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 18:30:34

US3492242

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:45:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Andrea Wendrow (b) (4)	09 Oct 2020 18:30:34
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:45:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:40
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 18:30:34

US3492242

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:45:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:40
User entered '9 Oct 2020'	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 18:30:34

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:45:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Andrea Wendrow (b) (4)	09 Oct 2020 18:30:34

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:45:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:40
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 14:48:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 14:48:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:48:42
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:30:34
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 18:30:34

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:45:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11OCT2020 is recorded under Illness Visit Day 7 visit in EDC, however the same is reported with date 12OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 10:31:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:40
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11OCT2020 is recorded under Illness Visit Day 7 visit in EDC, however the same is reported with date 12OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'correct in medidata and PPD processing log, will have lab update ' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	05 Nov 2020 22:53:37
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11OCT2020 is recorded under Illness Visit Day 7 visit in EDC, however the same is reported with date 12OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:45:36
User entered '11 Oct 2020' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:48:42
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 18:30:34

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:45:27

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation requery: Saliva: Per site response, "Oct 13 is correct". Per PPD portal, swab sample was collected on 13OCT2020 at illness visit; however, corresponding swab sample for 13OCT2020 is missing in EDC. Kindly confirm if swab sample was collected on 13OCT2020 for illness visit, if yes, update as appropriate' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 04:55:11
Query 'Per GCL Lab Reconciliation requery: Saliva: Per site response, "Oct 13 is correct". Per PPD portal, swab sample was collected on 13OCT2020 at illness visit; however, corresponding swab sample for 13OCT2020 is missing in EDC. Kindly confirm if swab sample was collected on 13OCT2020 for illness visit, if yes, update as appropriate' answered with 'yes, it was the day 9 saliva collection, this form. Are we missing something? We are not clear on what you are asking' (Site from DM).	Andrea Wendrow (b) (4)	24 Nov 2020 16:02:49
User opened query 'Per GCL Lab Reconciliation requery: Saliva: Per site response, "Oct 13 is correct". Per PPD portal, swab sample was collected on 13OCT2020 at illness visit; however, corresponding swab sample for 13OCT2020 is missing in EDC. Kindly confirm if swab sample was collected on 13OCT2020 for illness visit, if yes, update as appropriate' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:57:18
User accepted default value 'Day 9 (Day 9)'	Andrea Wendrow (b) (4)	09 Oct 2020 18:30:34

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:45:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:40
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 14:48:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 14:48:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	14 Oct 2020 14:48:42
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:30:34
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 18:30:34

US3492242

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:45:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
Query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "Oct 13 is correct". Per PPD portal, swab sample was collected on 13OCT2020 at illness visit; however, corresponding swab sample for 13OCT2020 is missing in EDC. Kindly confirm if swab sample was collected on 13OCT2020 for illness visit, if yes, update as appropriate.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 07:57:06
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "Oct 13 is correct". Per PPD portal, swab sample was collected on 13OCT2020 at illness visit; however, corresponding swab sample for 13OCT2020 is missing in EDC. Kindly confirm if swab sample was collected on 13OCT2020 for illness visit, if yes, update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:59:35
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 12OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:59:35
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 12OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Oct 13 is correct' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 20:57:22
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 12OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:32:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:40

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:45:27

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020' reason for change: Data Entry Error	Diana Bahena (b) (4)	14 Oct 2020 14:48:42
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	09 Oct 2020 18:30:34
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:45:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Andrea Wendrow (b) (4)	09 Oct 2020 18:30:34

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:45:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:40
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 14:44:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 14:44:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 14:44:09
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:30:34
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 18:30:34

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:45:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18OCT2020 is recorded under Illness Visit Day 14 visit in EDC, however the same is reported with date 19OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 10:31:52
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:40
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18OCT2020 is recorded under Illness Visit Day 14 visit in EDC, however the same is reported with date 19OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'correct in medidata and PPD processing log, will have lab update ' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	05 Nov 2020 22:54:51
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18OCT2020 is recorded under Illness Visit Day 14 visit in EDC, however the same is reported with date 19OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:46:15
User entered '18 Oct 2020' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 14:44:09
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 18:30:34

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:45:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Andrea Wendrow (b) (4)	09 Oct 2020 18:30:34

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:45:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:40
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 22:03:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Nov 2020 22:03:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 22:03:57
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:30:34
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 18:30:34

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:45:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25OCT2020 is recorded under Illness Visit Day 21 visit in EDC, however the same is reported with date 26OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 08:29:42
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25OCT2020 is recorded under Illness Visit Day 21 visit in EDC, however the same is reported with date 26OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'this is correct' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	11 Nov 2020 04:10:53
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:40
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25OCT2020 is recorded under Illness Visit Day 21 visit in EDC, however the same is reported with date 26OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 06:42:35
User entered '25 Oct 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 22:03:57
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 18:30:34

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:45:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Andrea Wendrow (b) (4)	09 Oct 2020 18:30:34

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:45:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Nov 2020 04:09:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 04:09:20
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 04:09:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 04:09:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:40
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:30:34
User entered empty.	Andrea Wendrow (b) (4)	09 Oct 2020 18:30:34
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:45:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:40
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 18:30:34

US3492242

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:55
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:47:11

US3492242

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:55
User entered '05 Oct 2020'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:47:11

US3492242

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[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 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:55
User entered 'Home (Home)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:47:11

US3492242

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User entered 'SICKD1'	System	05 Oct 2020 21:47:11

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:02
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:48:12

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:02
User entered '05 Oct 2020'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:48:12

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:02
User entered '12:35'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:48:12

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User entered '05 Oct 2020 12:35'	System	05 Oct 2020 21:48:12

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:02
User entered missing code ND - Not Done.	Diana Bahena (b) (4)	05 Oct 2020 21:48:12
DataPoint set to visible.	(b) (4) System	05 Oct 2020 21:47:11

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:02
User entered missing code ND - Not Done.	Diana Bahena (b) (4)	05 Oct 2020 21:48:12
DataPoint set to visible.	(b) (4) System	05 Oct 2020 21:47:11

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:02
User entered '99.1' F	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:48:12

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:02
User entered 'Oral (Oral)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:48:12

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:02
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:48:12

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:02
User entered '83'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:48:12

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User entered 'bpm'	System	05 Oct 2020 21:48:12

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:02
User entered '18'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:48:12

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User entered 'breaths/min'	System	05 Oct 2020 21:48:12

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:02
User entered '170'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:48:12

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User entered 'mmHg'	System	05 Oct 2020 21:48:12

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:02
User entered '90'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:48:12

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User entered 'mmHg'	System	05 Oct 2020 21:48:12

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41

US3492242

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41

US3492242

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:07
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:48:22

US3492242

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:07
User entered '05 Oct 2020'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:48:22

US3492242

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:45:27

[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 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:32
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:48:34

US3492242

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:45:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:32
User entered '05 Oct 2020'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:48:34

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	20 Dec 2020 18:28:14

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:28:14

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	20 Dec 2020 18:28:14

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	20 Dec 2020 18:28:14

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	20 Dec 2020 18:28:28

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	20 Dec 2020 18:28:28

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:28:28

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
User entered empty.	System	20 Dec 2020 18:28:28

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:28:28

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	20 Dec 2020 18:28:28

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:28:28

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:28:28

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Dec 2020 18:28:28

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:28:28

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Dec 2020 18:28:28

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	20 Dec 2020 18:28:28

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Dec 2020 18:28:28

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:28:28

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Dec 2020 18:28:28

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	20 Dec 2020 18:28:34

US3492242

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Andrea Wendrow (b) (4)	20 Dec 2020 18:28:34

US3492242

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:45:27

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	20 Dec 2020 18:28:43

US3492242

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:45:27

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:07:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	20 Dec 2020 18:28:43

US3492242

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

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 17:19:29

US3492242

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

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '2 Feb 2021'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 17:19:29

US3492242

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

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Clinic (Clinic)'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 17:19:29

US3492242

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

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 17:19:29

US3492242

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:27

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '2 Feb 2021'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 17:19:59

US3492242

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:27

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	07 Mar 2021 18:01:33
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 19:53:12

US3492242

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:27

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 17:19:59

US3492242

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:27

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
Amendment Manager inserted this DataPoint.	Andrea Wendrow (b) (4)	07 Mar 2021 18:01:33
	(b) (4)	
	System	06 Mar 2021 19:53:12

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:27

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '2 Feb 2021'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 17:19:59

US3492242

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:27

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Placebo (Placebo)'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 17:19:59

US3492242

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:27

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Placebo (Placebo)'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 17:19:59

US3492242

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:27

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Not Administered (NA)'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 17:19:59

US3492242

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:27

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 17:19:59

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:27

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered '1'	System	02 Feb 2021 17:19:59

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

Form: Unblinding

Generated On: 11 Aug 2021 22:45:27

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'I'	System	02 Feb 2021 17:19:59

US3492242

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered empty.	System	02 Feb 2021 18:32:53
DataPoint set to visible.	System	02 Feb 2021 17:19:59

US3492242

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:27

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered empty.	System	02 Feb 2021 18:32:53
DataPoint set to visible.	System	02 Feb 2021 17:19:59

US3492242

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User accepted default value 'Pre-Dose (PREDOSE)'	Nusirat Williams (b) (4)	02 Feb 2021 18:32:53
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '2 Feb 2021'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '12:15'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered '2 Feb 2021 12:15'	System	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '98.3' F	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Other (Other)'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'TYMPANIC'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '78'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'bpm'	System	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '16'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'breaths/min'	System	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '168'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'mmHg'	System	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '92'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'mmHg'	System	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:45:27

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered empty.	System	02 Feb 2021 18:32:53
DataPoint set to visible.	System	02 Feb 2021 17:19:59

US3492242

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User accepted default value 'Post-Dose (POSTDOSE)'	Nusirat Williams (b) (4) (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)' reason for change: New Information	Gizelle Alvarez (b) (4)	02 Feb 2021 19:17:34
User entered 'No (N)'	Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '2 Feb 2021' reason for change: New Information	Gizelle Alvarez (b) (4)	02 Feb 2021 19:17:34
User entered empty.	Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '12:55' reason for change: New Information	Gizelle Alvarez (b) (4)	02 Feb 2021 19:17:34
User entered empty.	Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered '2 Feb 2021 12:55'	System	02 Feb 2021 19:17:34
User entered empty.	System	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '36.8' C reason for change: New Information	Gizelle Alvarez (b) (4)	02 Feb 2021 19:17:34
User entered empty.	Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Other (Other)' reason for change: New Information	Gizelle Alvarez (b) (4)	02 Feb 2021 19:17:34
User entered empty.	Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'tympanic' reason for change: New Information	Gizelle Alvarez (b) (4)	02 Feb 2021 19:17:34
User entered empty.	Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '62' reason for change: New Information	Gizelle Alvarez (b) (4)	02 Feb 2021 19:17:34
User entered empty.	Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'bpm'	System	02 Feb 2021 19:17:34
User entered empty.	System	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '18' reason for change: New Information	Gizelle Alvarez (b) (4)	02 Feb 2021 19:17:34
User entered empty.	Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'breaths/min'	System	02 Feb 2021 19:17:34
User entered empty.	System	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '155' reason for change: New Information	Gizelle Alvarez (b) (4)	02 Feb 2021 19:17:34
User entered empty.	Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'mmHg'	System	02 Feb 2021 19:17:34
User entered empty.	System	02 Feb 2021 18:32:53

US3492242

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '92' reason for change: New Information	Gizelle Alvarez (b) (4)	02 Feb 2021 19:17:34
User entered empty.	Nusirat Williams (b) (4)	02 Feb 2021 18:32:53

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'mmHg'	System	02 Feb 2021 19:17:34
User entered empty.	System	02 Feb 2021 18:32:53

US3492242

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:33:00

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '2 Feb 2021'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:33:00

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	02 Feb 2021 19:16:10

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Gizelle Alvarez (b) (4)	02 Feb 2021 19:16:10

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Gizelle Alvarez (b) (4)	02 Feb 2021 19:16:10

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'mRNA-1273'	System	02 Feb 2021 19:16:10
DataPoint set to visible.	System	02 Feb 2021 17:19:59

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '2 Feb 2021'	Gizelle Alvarez (b) (4)	02 Feb 2021 19:16:10

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '12:42'	Gizelle Alvarez (b) (4)	02 Feb 2021 19:16:10

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered '2 Feb 2021 12:42'	System	02 Feb 2021 19:16:10

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Left Arm (LEFT ARM)'	Gizelle Alvarez (b) (4)	02 Feb 2021 19:16:10

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'ONCE'	System	02 Feb 2021 19:16:10

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 19:16:10

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'No (N)'	(b) (4) Marla Schwarber (b) (4)	02 Feb 2021 18:36:59

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Marla Schwarber (b) (4)	02 Feb 2021 18:36:59

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Marla Schwarber (b) (4)	02 Feb 2021 18:36:59

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered empty.	System	02 Feb 2021 18:36:59

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:45:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:39:53

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:45:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '2 Feb 2021'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:39:53

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:45:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '12:05'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:39:53

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:45:27

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered '2 Feb 2021 12:05'	System	02 Feb 2021 18:39:53

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	02 Feb 2021 18:39:41

US3492242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'I'	System	02 Feb 2021 18:39:41

US3492242

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	09 Feb 2021 16:15:03

US3492242

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '9 Feb 2021'	Nia Moragne-O'Neal (b) (4)	09 Feb 2021 16:15:03

US3492242

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	09 Feb 2021 16:15:03

US3492242

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Nia Moragne-O'Neal (b) (4)	09 Feb 2021 16:15:03

US3492242

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	09 Feb 2021 16:15:06

US3492242

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'I'	System	09 Feb 2021 16:15:06

US3492242

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'I'	System	09 Feb 2021 16:15:06
DataPoint set to visible.	System	09 Feb 2021 16:15:06

US3492242

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4)	04 Mar 2021 17:17:48

US3492242

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '4 Mar 2021'	Gizelle Alvarez (b) (4)	04 Mar 2021 17:17:48

US3492242

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Clinic (Clinic)'	Gizelle Alvarez (b) (4)	04 Mar 2021 17:17:48

US3492242

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'OLD29'	System	04 Mar 2021 17:17:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User accepted default value 'Pre-Dose (PREDOSE)'	Gizelle Alvarez (b) (4) (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '4 Mar 2021'	Gizelle Alvarez (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '11:24'	Gizelle Alvarez (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered '4 Mar 2021 11:24'	System	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
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)	
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 by data change (Site from System).	System	04 Mar 2021 17:39:09
User entered '36.0' C reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	04 Mar 2021 17:39:09
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).	(b) (4)	
User entered '36.0' F	System	04 Mar 2021 17:38:48
	Gizelle Alvarez (b) (4)	04 Mar 2021 17:38:48
	(b) (4)	

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Other (Other)'	Gizelle Alvarez (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'TYMPANIC'	Gizelle Alvarez (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '80'	Gizelle Alvarez (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'bpm'	System	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '16'	Gizelle Alvarez (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'breaths/min'	System	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '177'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'mmHg'	System	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:24:19
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Gizelle Alvarez (b) (4) (b) (4)	04 Mar 2021 17:39:31
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		04 Mar 2021 17:38:48
User entered '117'	Gizelle Alvarez (b) (4) (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'mmHg'	System	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User accepted default value 'Post-Dose (POSTDOSE)'	Gizelle Alvarez (b) (4) (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:02:05
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 17:38:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 17:38:52
User entered 'No (N)' reason for change: Data Entry Error	Gizelle Alvarez (b) (4) (b) (4)	04 Mar 2021 17:38:52
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 17:38:48
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '4 Mar 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:02:05
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '11:55' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:02:05
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered '4 Mar 2021 11:55'	System	04 Mar 2021 18:02:05
User entered empty.	System	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '97.8' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:02:05
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User closed query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	(b) (4)	
User entered 'Other (Other)' reason for change: Data Entry Error	System	04 Mar 2021 18:02:15
User opened query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).		
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 18:02:05
User entered empty.	Gizelle Alvarez (b) (4)	04 Mar 2021 17:38:48
	(b) (4)	

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'TMPANIC' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:02:05
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '68' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:02:05
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'bpm'	System	04 Mar 2021 18:02:05
User entered empty.	System	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '18' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:02:05
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'breaths/min'	System	04 Mar 2021 18:02:05
User entered empty.	System	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '169' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:02:05
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'mmHg'	System	04 Mar 2021 18:02:05
User entered empty.	System	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '97' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:02:05
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'mmHg'	System	04 Mar 2021 18:02:05
User entered empty.	System	04 Mar 2021 17:38:48

US3492242

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4)	04 Mar 2021 17:18:02

US3492242

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '4 Mar 2021'	Gizelle Alvarez (b) (4)	04 Mar 2021 17:18:02

US3492242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:02:45

US3492242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:02:45

US3492242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:02:45

US3492242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'mRNA-1273'	System	04 Mar 2021 18:02:45
DataPoint set to visible.	System	09 Feb 2021 16:15:06

US3492242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:02:45

US3492242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '11:53'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:02:45

US3492242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered '4 Mar 2021 11:53'	System	04 Mar 2021 18:02:45

US3492242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:02:45

US3492242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'ONCE'	System	04 Mar 2021 18:02:45

US3492242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:45:27

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'INTRAMUSCULAR'	System	04 Mar 2021 18:02:45

US3492242

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:15:27

US3492242

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'I'	System	18 Feb 2021 17:15:27

US3492242

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:16:01

US3492242

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
	System	11 Mar 2021 16:22:53
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	11 Mar 2021 16:22:53
User entered '11 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 16:22:53
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	04 Mar 2021 18:02:45
User entered '18 Feb 2021'	(b) (4), (b) (6)	18 Feb 2021 17:16:01

US3492242

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:16:01

US3492242

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:45:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:16:01

US3492242

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:16:28

US3492242

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:45:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:00:16
User entered 'I'	System	18 Feb 2021 17:16:28

US3492242

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	(b) (4) System	30 Apr 2021 17:30:16
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	30 Apr 2021 17:27:25
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	30 Apr 2021 17:25:32

US3492242

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System). User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	01 May 2021 10:50:45 30 Apr 2021 21:45:25
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'OL-D57 visit completed out of window ' (Site from System).	(b) (4), (b) (6)	30 Apr 2021 17:30:35
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	30 Apr 2021 17:30:16
User entered '30 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 17:30:16
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	30 Apr 2021 17:27:25
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	30 Apr 2021 17:27:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 17:27:25
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	30 Apr 2021 17:25:32
User entered '30 Apr 2021'	(b) (4), (b) (6)	30 Apr 2021 17:25:32

US3492242

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
	(b) (4)	
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	30 Apr 2021 17:30:16
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 17:30:16
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	30 Apr 2021 17:27:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 17:27:25
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Apr 2021 17:25:32

US3492242

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:45:27

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Apr 2021 17:25:32

US3492242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:31:10

US3492242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '30 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:31:10

US3492242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '11:52'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:31:10

US3492242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Apr 2021 11:52'	System	30 Apr 2021 17:31:10

US3492242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:31:10

US3492242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:31:10

US3492242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:31:10

US3492242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '63'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:31:10

US3492242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Apr 2021 17:31:10

US3492242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '16'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:31:10

US3492242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Apr 2021 17:31:10

US3492242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '186'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:31:10

US3492242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Apr 2021 17:31:10

US3492242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '97'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:31:10

US3492242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:45:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Apr 2021 17:31:10

US3492242

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:31:17

US3492242

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:45:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:31:17

US3492242

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:31:31

US3492242

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '30 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:31:31

US3492242

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
User entered '12:17'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:31:31

US3492242

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:45:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Apr 2021 12:17'	System	30 Apr 2021 17:31:31

US3492242

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:45:27

[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 2; 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)	13 Apr 2021 15:07:00
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 2; 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 'no per query requests and resolution, this was considered part of symptoms of COVID infection therefore, removed as an AE or SAR.' (Site from DM).	Andrea Wendrow (b) (4)	12 Apr 2021 17:07:31
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 2; 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 05:11:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:58
User entered 'Yes (Y)'	Addis Mekonnen (b) (4)	30 Sep 2020 19:57:05

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:00:22
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:20:51
User entered	System	04 Oct 2020 14:20:46
'USA-US101-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	04 Oct 2020 14:20:46

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:00:22
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (COUGH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:11:19
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (COUGH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	01 Nov 2020 22:06:52
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (COUGH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:52:18
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 20:20:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 20:20:44
Data point term sent to Coder	System	03 Oct 2020 20:19:57
User entered 'COVID-19 infection'	Andrea Wendrow (b) (4)	03 Oct 2020 20:19:53
	(b) (4)	

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User closed query 'PV Query: Please clarify event start date; start date should be when the subject began to experience symptoms. The event start date is reported as 05 Oct 2020; however, symptoms were reported on 29 Sep 2020.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:23:11
User entered '29 Sep 2020' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	17 Nov 2020 16:10:39
Query 'PV Query: Please clarify event start date; start date should be when the subject began to experience symptoms. The event start date is reported as 05 Oct 2020; however, symptoms were reported on 29 Sep 2020.' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4)	17 Nov 2020 16:09:30
DataPoint Un-verified.	Andrea Wendrow (b) (4)	17 Nov 2020 16:09:20
User entered '28 Sep 2020' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	17 Nov 2020 16:09:20
User opened query 'PV Query: Please clarify event start date; start date should be when the subject began to experience symptoms. The event start date is reported as 05 Oct 2020; however, symptoms were reported on 29 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:53:15
User closed query 'PV Query: Please consider updating start date of event to 29 Sep 2020 (start of Theraflu) or when the subject first experienced symptoms.' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 01:07:25
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:00:22
Query 'PV Query: Please consider updating start date of event to 29 Sep 2020 (start of Theraflu) or when the subject first experienced symptoms.' answered with 'prior query requested start date be date of positive COVID result from Moderna.' (Site from Safety).	Andrea Wendrow (b) (4)	06 Nov 2020 03:25:26
User opened query 'PV Query: Please consider updating start date of event to 29 Sep 2020 (start of Theraflu) or when the subject first experienced symptoms.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 16:54:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	09 Oct 2020 20:00:57
User entered '1 Oct 2020'	Andrea Wendrow (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered 'No (N)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 22:07:20
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 00:05:38
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 16:11:30
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'corrected' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 22:07:39
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'corrected' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 22:07:33
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	01 Nov 2020 22:07:20
User entered '22 Oct 2020' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 22:07:20
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 16:20:12
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
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)	03 Nov 2020 00:05:43
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 16:11:49
User closed query 'Per CDM: As Action Taken = IP Withdrawn, please complete Dosing Discontinuation form within EOS folder.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:11:48
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' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 22:13:33
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 22:11:32
Query 'Per CDM: As Action Taken = IP Withdrawn, please complete Dosing Discontinuation form within EOS folder.' answered with 'done' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 22:08:14
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 'done' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 22:08:10
User opened query 'Per CDM: As Action Taken = IP Withdrawn, please complete Dosing Discontinuation form within EOS folder.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:14:39
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	09 Oct 2020 20:00:57

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
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)	09 Oct 2020 16:22:52
User entered 'None (NONE)'	Andrea Wendrow (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:11:53
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'done' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 22:08:53
User entered '0' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 22:08:45
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:52:11
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:21:35
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' answered with 'The ppt had symptoms, for which he took CM, prior to the receipt of the result of Sarscov2 nasal swab. ' (Site from DM).	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 16:48:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:00:22
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:00:28
User entered '1' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 22:08:45
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:00:22
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 00:05:47
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4)	01 Nov 2020 22:08:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Andrea Wendrow (b) (4)	01 Nov 2020 22:07:51
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 16:20:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Andrea Wendrow (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[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 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:22
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User closed query 'PV Query: Please consider updating COVID symptom log as the subject reported taking medication (Theraflu) for cough.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:20:08
User closed query 'PV Query: Please provide baseline (23 Sep 2020) SARS COVID-19 test result.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 20:20:05
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:00:22
Query 'PV Query: Please consider updating COVID symptom log as the subject reported taking medication (Theraflu) for cough.' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	06 Nov 2020 03:27:00
Query 'PV Query: Please provide baseline (23 Sep 2020) SARS COVID-19 test result.' answered with 'negative baseline SARS COVID-19' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	06 Nov 2020 03:26:50
User entered 'negative baseline SARS COVID-19' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	06 Nov 2020 03:26:44
User opened query 'PV Query: Please consider updating COVID symptom log as the subject reported taking medication (Theraflu) for cough.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 16:55:03
User opened query 'PV Query: Please provide baseline (23 Sep 2020) SARS COVID-19 test result.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 16:54:36
User closed query 'PV Query: Please provide baseline (23 Sep 2020) SARS COVID-19 test result.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 00:05:55
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 00:05:52
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 00:05:50

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide baseline (23 Sep 2020) SARS COVID-19 test result.' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4)	01 Nov 2020 22:09:59
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4)	01 Nov 2020 22:09:51
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4)	01 Nov 2020 22:09:37
User opened query 'PV Query: Please provide baseline (23 Sep 2020) SARS COVID-19 test result.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 16:23:15
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 16:23:04
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 16:20:39
User entered empty.	Andrea Wendrow (b) (4)	03 Oct 2020 20:19:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:45:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 20:19:53

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 21:09:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 21:09:23
Data point term sent to Coder	System	29 Jan 2021 21:09:02
User entered 'worsening Hypertension'	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'Yes (Y)'	(b) (4) Michelle Agnoli (b) (4) (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'No (N)'	(b) (4) Michelle Agnoli (b) (4) (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'No (N)'	(b) (4) Michelle Agnoli (b) (4) (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered '22 Nov 2020'	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User closed query 'Per CDM: Response indicates 'start time removed per request'. However 0:00 is present which indicates exact mid night of 22 NOV 2020. Please leave the field blank per previous query. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 09:16:19
Query 'Per CDM: Response indicates 'start time removed per request'. However 0:00 is present which indicates exact mid night of 22 NOV 2020. Please leave the field blank per previous query. Thank you. ' answered with 'updated' (Site from DM).	Lorna Sanchez McCann (b) (4)	01 Feb 2021 20:59:17
User entered empty; reason for change Per Query Resolution	Lorna Sanchez McCann (b) (4)	01 Feb 2021 20:58:43
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	01 Feb 2021 05:40:04
User opened query 'Per CDM: Response indicates 'start time removed per request'. However 0:00 is present which indicates exact mid night of 22 NOV 2020. Please leave the field blank per previous query. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:39:51
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'start time removed per request ' (Site from System).	Michelle Agnoli (b) (4) (b) (4)	29 Jan 2021 21:14:42
User entered '0:00' reason for change: Per Query Resolution	Michelle Agnoli (b) (4) (b) (4)	29 Jan 2021 21:14:27
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	29 Jan 2021 21:08:10
User entered '09:00'	Michelle Agnoli (b) (4) (b) (4)	29 Jan 2021 21:08:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 20:58:43
User entered '22 Nov 2020 0:00'	System	29 Jan 2021 21:14:27
User entered '22 Nov 2020 09:00'	System	29 Jan 2021 21:08:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'Yes (Y)'	(b) (4) Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'No (N)'	(b) (4) Michelle Agnoli (b) (4) (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered '0'	(b) (4) Michelle Agnoli (b) (4) (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered '0'	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered '0'	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	(b) (4) Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered '0'	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered '0'	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered '0'	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'Not Related (NOT RELATED)'	(b) (4) Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'Not Related (NOT RELATED)'	(b) (4) Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'None (NONE)'	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered '0'	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'I'	(b) (4) Michelle Agnoli (b) (4) (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered '0'	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'Patient was prescribed metoprolol in addition to his losartan to better control his hypertension.'	Michelle Agnoli (b) (4)	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 21:08:10

US3492242

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:45:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 21:08:10

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:45:27

[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 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:32:58

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:35:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:35:37
Data point term sent to Coder	System	23 Sep 2020 15:34:31
User entered 'Losartan'	(b) (4), (b) (6)	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered 'hypertension'	(b) (4), (b) (6)	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered '100'	(b) (4), (b) (6)	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered 'UN UNK 2019'	(b) (4), (b) (6)	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:45:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 15:33:33

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PHENYLE PHRINE HYDROCHLORIDE, PRODUCTSYNONYM: THERAFLU COLD & COUGH NIGHTTIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 13:21:39
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 Oct 2020 13:21:39
Data point term sent to Coder	System	15 Oct 2020 20:22:16
Data point term sent to Coder	System	15 Oct 2020 20:19:07
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	15 Oct 2020 20:19:02
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'completed' (Site from System).	Michelle Agnoli (b) (4) (b) (4)	15 Oct 2020 20:19:02
Data point term sent to Coder	System	15 Oct 2020 19:58:11
User entered 'THERAFLU {acetaminophen, dextromethorphan, phenylephrine}' reason for change: Per Query Resolution	Michelle Agnoli (b) (4) (b) (4)	15 Oct 2020 19:57:56
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4) (b) (4)	12 Oct 2020 14:25:13
Data point term sent to Coder	System	30 Sep 2020 20:51:12
User entered 'Theraflu'	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 20:50:24

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered 'No (N)' reason for change: Data Entry Error	Addis Mekonnen (b) (4) (b) (4)	05 Oct 2020 16:33:23
User entered 'Yes (Y)'	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 20:50:24

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User closed query 'Per ETRTR: Please consider if indication should be changed to COVID-19. Also if related, update AE CRF to indicate medication was dosed for AE COVID-19, thanks.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:19:32
Query 'Per ETRTR: Please consider if indication should be changed to COVID-19. Also if related, update AE CRF to indicate medication was dosed for AE COVID-19, thanks.' answered with 'Symptoms started 9/28, test on 10/3 that was positive for COVID-19. Yes, considered related, AE previously reported' (Site from CRA).	Michelle Agnoli (b) (4) (b) (4)	15 Oct 2020 20:50:08
User entered 'COUGH later found to be related to COVID-19' reason for change: New Information	Michelle Agnoli (b) (4) (b) (4)	15 Oct 2020 20:21:29
User opened query 'Per ETRTR: Please consider if indication should be changed to COVID-19. Also if related, update AE CRF to indicate medication was dosed for AE COVID-19, thanks.' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 21:46:29
User entered 'Cough'	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 20:50:24

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
	(b) (4)	
DataPoint Un-verified.	Marla Schwarber (b) (4)	15 Jan 2021 17:48:37
	(b) (4)	
User entered '500/20/10' reason for change: Data Entry Error	Marla Schwarber (b) (4)	15 Jan 2021 17:48:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered 'I'	Addis Mekonnen (b) (4)	30 Sep 2020 20:50:24
	(b) (4)	

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
	(b) (4)	
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	15 Jan 2021 17:48:37
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	15 Jan 2021 17:47:38
DataPoint Un-verified.	Marla Schwarber (b) (4)	15 Jan 2021 17:47:38
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Marla Schwarber (b) (4)	15 Jan 2021 17:47:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered 'Other (OTHER)'	Addis Mekonnen (b) (4)	30 Sep 2020 20:50:24
	(b) (4)	

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User closed query 'Per CDM re-query: Per previous query, only the units should be recorded in this field (e.g. MG). The dose should be recorded in the Dose per Administration field. For combination doses, it should be recorded with a / separating each component e.g. 500/20/10. Please update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 06:54:35
Query 'Per CDM re-query: Per previous query, only the units should be recorded in this field (e.g. MG). The dose should be recorded in the Dose per Administration field. For combination doses, it should be recorded with a / separating each component e.g. 500/20/10. Please update as appropriate.' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	15 Jan 2021 17:48:46
User entered empty; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	15 Jan 2021 17:48:37
User entered '500/20/10' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	15 Jan 2021 17:47:38
User opened query 'Per CDM re-query: Per previous query, only the units should be recorded in this field (e.g. MG). The dose should be recorded in the Dose per Administration field. For combination doses, it should be recorded with a / separating each component e.g. 500/20/10. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 11:56:50
User closed query 'Per DM CLR: Please remove extraneous data and ensure that only the actual unit is captured in this field. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 11:56:50
Query 'Per DM CLR: Please remove extraneous data and ensure that only the actual unit is captured in this field. Update as appropriate. ' answered with '-----corrected. Thank you-----' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 18:05:14
DataPoint Un-verified.	(b) (4), (b) (6)	12 Jan 2021 18:04:53
User entered '500mg / 20mg / 10mg' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 18:04:53

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please remove extraneous data and ensure that only the actual unit is captured in this field. Update as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 17:11:27
	(b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered 'Open 1 packet and mix the contents into 8 oz. of hot water.'	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 20:50:24

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered 'as needed (PRN)'	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 20:50:24

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered empty.	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 20:50:24

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered 'Oral (ORAL)'	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 20:50:24

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered empty.	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 20:50:24

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 29 SEP 2020.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 11:01:46
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 29 SEP 2020.' answered with 'this is correct. Previous query requested cough AE be removed since related to COVID infection. Theraflu was started on 29Sep2020' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	11 Nov 2020 04:17:09
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:00:36
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 29 SEP 2020.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:39:54
User entered '29 Sep 2020'	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 20:50:24

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered '0'	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 20:50:24

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
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 11:57:24
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 '-----continues as PRN medication-----' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 18:06:13
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 17:11:06
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered 'Yes (Y)'	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 20:50:24

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:36
User entered empty.	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 20:50:24

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:00:20
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Lorna Sanchez McCann (b) (4)	16 Nov 2020 20:29:40
DataPoint Un-verified.	Lorna Sanchez McCann (b) (4)	16 Nov 2020 20:29:28
User entered 'No (N)' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	16 Nov 2020 20:29:28
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:00:36
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:40:15
User entered 'Yes (Y)' reason for change: Per Query Resolution	Michelle Agnoli (b) (4) (b) (4)	15 Oct 2020 20:23:15
User entered 'No (N)'	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 20:50:24

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 20:50:24

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 20:50:24

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:45:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 20:50:24

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Feb 2021 23:55:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Feb 2021 23:55:32
Data point term sent to Coder	System	01 Feb 2021 21:00:21
Coding entries removed.	Lorna Sanchez McCann	01 Feb 2021 21:00:05
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:49:04
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'done' (Site from DM).	Michelle Agnoli (b) (4)	29 Jan 2021 21:04:32
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:11:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Nov 2020 16:26:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	25 Nov 2020 16:26:19
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	25 Nov 2020 16:23:03
User entered 'metoprolol'	Lorna Sanchez McCann	25 Nov 2020 16:22:41
	(b) (4)	

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User closed query 'Per CDM re-query: Thank you for adding the 'WORSENING HYPERTENSION' in AE page. Please update the con med indication to reflect the worsening of the condition. Please update else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 05:11:53
Query 'Per CDM re-query: Thank you for adding the 'WORSENING HYPERTENSION' in AE page. Please update the con med indication to reflect the worsening of the condition. Please update else clarify. ' answered with 'updated' (Site from DM).	Lorna Sanchez McCann (b) (4)	01 Feb 2021 21:00:12
User entered 'worsening HYPERTENSION' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	01 Feb 2021 21:00:05
User opened query 'Per CDM re-query: Thank you for adding the 'WORSENING HYPERTENSION' in AE page. Please update the con med indication to reflect the worsening of the condition. Please update else clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:50:53
User entered 'hypertension'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered '100'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'mg (mg)'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'once daily (QD)'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'Oral (ORAL)'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered '22 Nov 2020'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered '0'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
Signature has been broken.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:24:34
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	11 Mar 2021 16:24:34
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
Signature has been broken.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:24:34
User entered '06 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	11 Mar 2021 16:24:34
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User entered '1'	System	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User entered '1'	System	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:45:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:03
User entered '804 (804)'	System	25 Nov 2020 16:22:41

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Mar 2021 16:27:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 16:27:53
Data point term sent to Coder	System	11 Mar 2021 16:27:07
User entered 'metoprolol'	(b) (4), (b) (6)	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '200'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '06 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:45:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Mar 2021 16:26:17

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: ROBITUSSIN DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 09:48:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 09:48:53
Data point term sent to Coder Coding entries removed.	System	07 Apr 2021 21:44:37
	Marla Schwarber (b) (4)	07 Apr 2021 21:43:40
Signature has been broken.	(b) (4)	
	Marla Schwarber (b) (4)	07 Apr 2021 21:43:40
User entered 'ROBITUSSIN DM (Dextromethorphan Hbr 20 mg/Guaifenesin 200 mg)' reason for change: New Information	(b) (4)	
User signature succeeded.	Marla Schwarber (b) (4)	07 Apr 2021 21:43:40
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: ROBITUSSIN [GUAIFENESIN] - version WHODrug-Global-B3\\202003.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 11:30:29
Data point term sent to Coder	System	15 Mar 2021 15:48:54
User entered 'robitussin'	Lorna Sanchez McCann	15 Mar 2021 15:47:54
	(b) (4)	

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Cough, related to covid 19 infection'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:38
User closed query 'Per DM CLR: Please provide dose in MG instead of ML, as there are various dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:29:44
Query 'Per DM CLR: Please provide dose in MG instead of ML, as there are various 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)	07 Apr 2021 21:43:48
Signature has been broken.	Marla Schwarber (b) (4) (b) (4)	07 Apr 2021 21:43:40
User entered '20/200' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	07 Apr 2021 21:43:40
User opened query 'Per DM CLR: Please provide dose in MG instead of ML, as there are various dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 02:26:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:53:47
User entered '20'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:38
Signature has been broken.	Marla Schwarber (b) (4)	07 Apr 2021 21:43:40
User entered 'mg (mg)' reason for change: New Information	Marla Schwarber (b) (4)	07 Apr 2021 21:43:40
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'mL (mL)'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered empty.	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'unknown (UNKNOWN)'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered empty.	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Oral (ORAL)'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered empty.	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '07 Oct 2020'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '0'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '14 Oct 2020'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User entered empty.	System	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User entered empty.	System	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:45:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:11
User entered empty.	System	15 Mar 2021 15:47:54

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 11:48:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 11:48:59
Data point term sent to Coder	System	07 Apr 2021 21:46:40
User closed query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	System	07 Apr 2021 21:46:39
Query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'updated' (Site from System).	Marla Schwarber (b) (4)	07 Apr 2021 21:46:39
Coding entries removed.	Marla Schwarber (b) (4)	07 Apr 2021 21:46:15
Signature has been broken.	Marla Schwarber (b) (4)	07 Apr 2021 21:46:15
User entered 'NYQUIL cold and flu (Acetaminophen 650 mg/Dextromethorphan Hbr 30 mg/Doxylamine Succinate 12.5 mg per 30 mil)' reason for change: New Information	Marla Schwarber (b) (4)	07 Apr 2021 21:46:15
User opened query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	Coder Import (b) (4)	06 Apr 2021 15:02:52
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 15:53:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 15:53:57
Data point term sent to Coder	System	15 Mar 2021 15:53:06
User entered 'nyquil'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'cough, related to covid 19 infection'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:38
User closed query 'Per DM CLR: Please provide dose in MG instead of ML, as there are various dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:29:57
Query 'Per DM CLR: Please provide dose in MG instead of ML, as there are various 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)	07 Apr 2021 21:46:47
Signature has been broken.	Marla Schwarber (b) (4) (b) (4)	07 Apr 2021 21:46:15
User entered '650/30/12.5' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	07 Apr 2021 21:46:15
User opened query 'Per DM CLR: Please provide dose in MG instead of ML, as there are various dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 02:26:20
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:53:47
User entered '30'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:38
Signature has been broken.	Marla Schwarber (b) (4)	07 Apr 2021 21:46:15
User entered 'mg (mg)' reason for change: New Information	Marla Schwarber (b) (4)	07 Apr 2021 21:46:15
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'mL (mL)'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered empty.	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'unknown (UNKNOWN)'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered empty.	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'Oral (ORAL)'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered empty.	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '04 Oct 2020'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '0'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered '07 Oct 2020'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:47
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User entered empty.	System	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User entered empty.	System	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:45:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:14
User entered empty.	System	15 Mar 2021 15:52:06

US3492242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:45:27

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:00:45
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 15:36:26

US3492242

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:45:27

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '5 Oct 2020'	(b) (4) Andrea Wendrow (b) (4)	01 Nov 2020 22:11:32

US3492242

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:45:27

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'Due to SARS-COV-2 (COVID)'	Andrea Wendrow (b) (4)	01 Nov 2020 22:11:32

US3492242

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:45:27

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 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered empty.	Andrea Wendrow (b) (4)	01 Nov 2020 22:11:32

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'USA-US101-2020-MRNA-1273-P301000003'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'Richard'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'Novak'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered '808 S. Wood St'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'Chicago'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'IL'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered '60612'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 00:06:04
User entered 'US'	System	04 Oct 2020 14:21:14

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
	(b) (4)	
User entered '4'	System	18 Nov 2020 20:24:22
User entered '3'	System	09 Nov 2020 20:20:32
User entered '2'	System	03 Nov 2020 00:06:14
User entered '1'	System	04 Oct 2020 14:21:14

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'USA-US101-2020-MRNA-1273-P301000003'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'Richard'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'Novak'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered '808 S. Wood St'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'Chicago'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'IL'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered '60612'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 00:06:04
User entered 'US'	System	04 Oct 2020 14:21:14

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
	(b) (4)	
User entered '4'	System	18 Nov 2020 20:24:22
User entered '3'	System	09 Nov 2020 20:20:32
User entered '2'	System	03 Nov 2020 00:06:14
User entered '1'	System	04 Oct 2020 14:21:14

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:45:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
User entered '04/Oct/2020 10:21'	System	04 Oct 2020 14:21:14

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:45:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 00:06:04
User entered 'I'	(b) (4), (b) (6)	04 Oct 2020 14:21:14

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'USA-US101-2020-MRNA-1273-P301000003'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'Richard'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'Novak'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered '808 S. Wood St'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'Chicago'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'IL'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered '60612'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 00:06:04
User entered 'US'	System	04 Oct 2020 14:21:14

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
	(b) (4)	
User entered '4'	System	18 Nov 2020 20:24:22
User entered '3'	System	09 Nov 2020 20:20:32
User entered '2'	System	03 Nov 2020 00:06:14
User entered '1'	System	04 Oct 2020 14:21:14

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:45:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
User entered '03/Nov/2020 00:06'	System	03 Nov 2020 00:06:14

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:45:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:20:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:53
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 00:06:14

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'USA-US101-2020-MRNA-1273-P301000003'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'Richard'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'Novak'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered '808 S. Wood St'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'Chicago'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'IL'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered '60612'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 00:06:04
User entered 'US'	System	04 Oct 2020 14:21:14

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
	(b) (4)	
User entered '4'	System	18 Nov 2020 20:24:22
User entered '3'	System	09 Nov 2020 20:20:32
User entered '2'	System	03 Nov 2020 00:06:14
User entered '1'	System	04 Oct 2020 14:21:14

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:45:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '09/Nov/2020 20:20'	(b) (4) System	09 Nov 2020 20:20:32

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:45:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 20:24:09
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 20:20:32

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'USA-US101-2020-MRNA-1273-P301000003'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'No (N)'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'Richard'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'Novak'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered '808 S. Wood St'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'Chicago'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered 'IL'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 14:21:07
User entered '60612'	System	04 Oct 2020 14:20:46

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:53
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 00:06:04
User entered 'US'	System	04 Oct 2020 14:21:14

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:45:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
	(b) (4)	
User entered '4'	System	18 Nov 2020 20:24:22
User entered '3'	System	09 Nov 2020 20:20:32
User entered '2'	System	03 Nov 2020 00:06:14
User entered '1'	System	04 Oct 2020 14:21:14

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:45:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered '18/Nov/2020 20:24'	(b) (4) System	18 Nov 2020 20:24:22

US3492242

Folder: SAE USA-US101-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:45:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:57
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:24:22