

US3492117 (Prod: UIC Project WISH CRS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:51:43

All time stamps listed in this document are displayed in GMT

US3492117

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 03:46:59

Generated On: 11 Aug 2021 22:51:43

[Participant ID](#)

US3492117

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

US3492117

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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 03:47:01

Generated On: 11 Aug 2021 22:51:43

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input checked="" type="radio"/> Male <input 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	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	HISPANIC
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 03:47:01

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Date of Informed Consent (<i>dd MMM yyyy</i>)	10 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 checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

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 03:47:01

Generated On: 11 Aug 2021 22:51:43

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Mar 2021 01:44:14

Generated On: 11 Aug 2021 22:51:43

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Mar 2021 01:44:14

Generated On: 11 Aug 2021 22:51:43

Condition	HYPERLIPIDEMIA
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: Medical History (3)

Data signed: (b) (4) 26 Mar 2021 01:44:14

Generated On: 11 Aug 2021 22:51:43

Condition	DERMAL FILLER INJECTION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Mar 2021 01:44:14

Generated On: 11 Aug 2021 22:51:43

Condition	SKIN COSMETIC PROCEDURE
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:50 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 13:50
Height (<i>xxx.x</i>)	147 cm
Weight (<i>xxx.x</i>)	52.9 kg
BMI (<i>xxx.x</i>)	24.48054 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	ND - Not Done
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 03:47:01

Generated On: 11 Aug 2021 22:51:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 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: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*) 10 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2007

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 03:47:01

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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

NOT EMPLOYED

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 03:47:01

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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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:47:16

Generated On: 11 Aug 2021 22:51:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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 03:47:16

Generated On: 11 Aug 2021 22:51:43

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

What was the participant's randomization number? 112999

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 03:47:17

Generated On: 11 Aug 2021 22:51:43

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 03:47:17

Generated On: 11 Aug 2021 22:51:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 13:50
Temperature (xxx.x)	99 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	EAR
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 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: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 03:47:17

Generated On: 11 Aug 2021 22:51:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 14:55
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	EAR
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	165 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 03:47:16

Generated On: 11 Aug 2021 22:51:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 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 03:47:01

Generated On: 11 Aug 2021 22:51:43

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 14:48 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 14:48

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 03:47:01

Generated On: 11 Aug 2021 22:51:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 SEP 2020

Collection time (00:00-23:59)

14:15 (24 HR)

Collection date and time (derived)

10 SEP 2020 14:15

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:30	10 SEP 2020 14:30
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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

10 SEP 2020 15:11

PC Open Date & Time

10 SEP 2020 15:08

PC Close Date & Time

10 SEP 2020 17:38

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °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	11 SEP 2020 09:11
PC Open Date & Time	10 SEP 2020 18:33
PC Close Date & Time	11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 08:11

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 08:35

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:51:43

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 08:26

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:51:43

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

97.9 °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

15 SEP 2020 07:40

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 08:41

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 10:00

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 15:11

PC Open Date & Time

10 SEP 2020 15:08

PC Close Date & Time

10 SEP 2020 17:38

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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

11 SEP 2020 09:13

PC Open Date & Time

10 SEP 2020 18:33

PC Close Date & Time

11 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

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

12 SEP 2020 08:12

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

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

13 SEP 2020 08:35

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

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

14 SEP 2020 08:26

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

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

15 SEP 2020 07:40

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

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

16 SEP 2020 08:41

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

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

17 SEP 2020 10:00

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 15:12
PC Open Date & Time	10 SEP 2020 15:08
PC Close Date & Time	10 SEP 2020 17:38

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 09:14
PC Open Date & Time	10 SEP 2020 18:33
PC Close Date & Time	11 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 08:13
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

48 of 2317

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 08:36
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

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 ☒

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 08:27
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

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 ☒

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 07:41
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

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 ☒

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 08:42
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

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 ☒

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 10:00
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3492117

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492117

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492117

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:44:14

Generated On: 11 Aug 2021 22:51:43

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

SUBJECT IN
ILLNESS/CONVALESCENCE

If Contact Not Made, please provide Comments

US3492117

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:47:17

Generated On: 11 Aug 2021 22:51:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 03:47:17

Generated On: 11 Aug 2021 22:51:43

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 11:55
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 03:47:17

Generated On: 11 Aug 2021 22:51:43

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	

US3492117

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:47:17

Generated On: 11 Aug 2021 22:51:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 03:47:17

Generated On: 11 Aug 2021 22:51:43

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?

US3492117

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:47:17

Generated On: 11 Aug 2021 22:51:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 OCT 2020

Collection time (00:00-23:59)

12:10 (24 HR)

Collection date and time (derived)

8 OCT 2020 12:10

US3492117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 03:47:17

Generated On: 11 Aug 2021 22:51:43

Collection date (dd MMM yyyy)			8 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:15	8 OCT 2020 12:15
Nasopharyngeal Swab 2	No		

US3492117

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:47:17

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492117

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492117

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:44:14

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:47:17

Generated On: 11 Aug 2021 22:51:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 03:47:17

Generated On: 11 Aug 2021 22:51:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	6 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	11:10 (24 HR)
Vital Signs Date and Time (derived)	6 NOV 2020 11:10
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492117

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:47:17

Generated On: 11 Aug 2021 22:51:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 NOV 2020

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

US3492117

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:47:17

Generated On: 11 Aug 2021 22:51:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

6 NOV 2020

Collection time (00:00-23:59)

11:20 (24 HR)

Collection date and time (derived)

6 NOV 2020 11:20

US3492117

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:47:17

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 08:02:26
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 21:07:10

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 11:45:46
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 01:18:11

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 07:30:34

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 05:06:41
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 11:23:39

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 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	26 DEC 2020 05:25:32
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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	05 JAN 2021 05:45:05
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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	11 JAN 2021 13:47:32
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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	16 JAN 2021 09:10:46
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 13:31:41

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	True
Nausea	True
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

30 JAN 2021 05:34:00

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 FEB 2021 08:41:41
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

13 FEB 2021 07:39:35

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 FEB 2021 02:42:57
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	27 FEB 2021 09:32:36
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 03:31:09
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

14 MAR 2021 00:26:37

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 05:41:52
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

27 MAR 2021 04:02:03

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 05:01:13

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 04:48:58

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 05:19:39

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 02:39:14

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 02:48:32

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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°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 ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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="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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 <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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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="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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 <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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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="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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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°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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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="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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	26 JAN 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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°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 ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐
Yes ☐

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

09 APR 2022 00:01

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13 APR 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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15 JUN 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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29 JUN 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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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02 JUL 2022 00:01

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06 JUL 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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13 JUL 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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20 JUL 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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27 JUL 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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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30 JUL 2022 00:01

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03 AUG 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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10 AUG 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

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17 AUG 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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24 AUG 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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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31 AUG 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 <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"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3492117

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:51:43

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
Yes	No	27 FEB 2021 20:58:05

US3492117

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492117

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492117

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492117

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:44:14

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492117

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 16:25:32

Generated On: 11 Aug 2021 22:51:43

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

Visit date (dd MMM yyyy)	26 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 16:25:32

Generated On: 11 Aug 2021 22:51:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:35 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 11:35
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (<i>xxx</i>)	69 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492117

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 16:25:32

Generated On: 11 Aug 2021 22:51:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 MAR 2021

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

US3492117

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 16:25:32

Generated On: 11 Aug 2021 22:51:43

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

Collection date (dd MMM yyyy)	26 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	11:35 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	26 MAR 2021 11:35
------------------------------------	-------------------

US3492117

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 16:25:32

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

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

03 MAY 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492117

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 15 Feb 2021 03:46:59

Generated On: 11 Aug 2021 22:51:43

Date of Contact	22 SEP 2020
Time of Contact	10:00
Date and Time of Contact (derived)	22 SEP 2020 10:00
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>

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

Symptom Day

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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 SEP 2020	
Assessment Not Done	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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US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

	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"/>

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	100.7 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

	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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 22 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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

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EAB) (1725)

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

	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 22 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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"/>

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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"/>

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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 checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 (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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Form: Symptom Log (5)

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input 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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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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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	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 (5)

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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)

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input 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 (6)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	101.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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) 15 Feb 2021 03:47:00

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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 (7)

Data signed: (b) (4) 15 Feb 2021 03:47:00

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input 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 (7)

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input 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 (7)

Data signed: (b) (4) 15 Feb 2021 03:47:00

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

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Form: Symptom Log (8)

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Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

	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	96 %	
O2 Saturation Units	%	
Temperature	99.7 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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Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 03:47:00

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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 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) 15 Feb 2021 03:47:00

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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 (9)

Data signed: (b) (4) 15 Feb 2021 03:47:00

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Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 03:47:00

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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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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 22 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	100.0 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 (10)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input 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 (10)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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 22 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

Symptom Day

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

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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

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Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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

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Form: Symptom Log (12)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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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Form: Symptom Log (12)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

	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	95 %	
O2 Saturation Units	%	
Temperature	102.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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 22 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

	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	96 %	
O2 Saturation Units	%	
Temperature	102.0 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 (13)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

Symptom Day

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

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	5 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	101.0 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 22 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 15 Feb 2021 03:46:59

Generated On: 11 Aug 2021 22:51:43

Date of Visit	23 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	23 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Feb 2021 03:46:59

Generated On: 11 Aug 2021 22:51:43

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Feb 2021 03:46:59

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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 22 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Feb 2021 03:46:59

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Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

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

Start Date

End Date

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 15 Feb 2021 03:46:59

Generated On: 11 Aug 2021 22:51:43

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	25 SEP 2020
Day 5	Yes	27 SEP 2020
Day 7	Yes	29 SEP 2020
Day 9	Yes	1 OCT 2020
Day 14	Yes	06 OCT 2020
Day 21	Yes	13 OCT 2020
Day 28	Yes	20 OCT 2020

US3492117

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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 checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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)	12:20 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 12:20
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	100.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492117

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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.

US3492117

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 03:47:00

Generated On: 11 Aug 2021 22:51:43

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 SEP 2020

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:46:59

Generated On: 11 Aug 2021 22:51:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 03:46:59

Generated On: 11 Aug 2021 22:51:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 OCT 2020
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 15:50
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	99 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:46:59

Generated On: 11 Aug 2021 22:51:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3492117

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 03:46:59

Generated On: 11 Aug 2021 22:51:43

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

20 OCT 2020

US3492117

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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

Visit date (dd MMM yyyy)	29 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3492117

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

Date of updated informed consent (<i>dd MMM yyyy</i>)	29 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	29 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input 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

US3492117

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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

US3492117

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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)	29 JAN 2021
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 11:35
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3492117

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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)	29 JAN 2021
Time of assessment (00:00-23:59)	12:30 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 12:30
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3492117

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

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JAN 2021

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

US3492117

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

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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) 29 JAN 2021

What was the treatment time? (00:00-23:59) 12:15 (24 HR)

Treatment Date and Time (derived) 29 JAN 2021 12:15

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

US3492117

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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

Collection date (dd MMM yyyy)	29 JAN 2021
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Collection time (00:00-23:59)	11:28 (24 HR)
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Collection date and time (derived)	29 JAN 2021 11:28
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US3492117

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

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

Collection date (dd MMM yyyy)	29 JAN 2021
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Collection time (00:00 - 23:59)	11:31
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Collection Date and Time (derived)	29 JAN 2021 11:31
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US3492117

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492117

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

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)	25 FEB 2021
Time of assessment (00:00-23:59)	11:09 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 11:09
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 12:15
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input checked="" type="checkbox"/>
If Other, specify	TYMPANIC
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3492117

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3492117

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

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) 25 FEB 2021

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

Treatment Date and Time (derived) 25 FEB 2021 12:12

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

US3492117

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:44:14

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492117

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:44:14

Generated On: 11 Aug 2021 22:51:43

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) 26 Apr 2021 16:25:32

Generated On: 11 Aug 2021 22:51:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 16:25:32

Generated On: 11 Aug 2021 22:51:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:35 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 11:35
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (<i>xxx</i>)	69 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492117

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 16:25:32

Generated On: 11 Aug 2021 22:51:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 MAR 2021

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

US3492117

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 16:25:32

Generated On: 11 Aug 2021 22:51:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 MAR 2021

Collection time (00:00-23:59)

11:35 (24 HR)

Collection date and time (derived)

26 MAR 2021 11:35

US3492117

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 03:46:59

Generated On: 11 Aug 2021 22:51:43

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Feb 2021 03:46:59

Generated On: 11 Aug 2021 22:51:43

AEID	USA-US101-2020-MRNA-1273-P30 1000001
Adverse event	COVID 19, CONFIRMED
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	22 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	5 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 (4)

Data signed: (b) (4) 15 Feb 2021 03:46:59

Generated On: 11 Aug 2021 22:51:43

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	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Feb 2021 03:46:59

Generated On: 11 Aug 2021 22:51:43

THE PARTICIPANT CALLED THE
CALL CENTER ON 9/23/2020
INDICATING SHE HAD FEVER
AND MYALGIAS OF HER UPPER
EXTREMITIES, SORE THROAT,
CHORIZA AND COUGH WHICH
BEGAN ON 9/22/2020. I DECIDED
THIS WOULD TRIGGER AN
ILLNESS VISIT. WE SENT THE
MOBILE TEAM TO ASSESS HER
AND COLLECT SAMPLES. THEY
INDICATED THE PARTICIPANT
TOOK IBUPROFEN 800MG WITH
MINIMAL RELIEF. THE NP
SWAB COLLECTED ON 9/23/2020
WAS SENT TO VIRACOR. THE
RESULTS CAME BACK ON 9/26
AS POSITIVE.
THE PARTICIPANT CALLED ME
ON 9/23 REPORTING A
TEMPERATURE EXCEEDING 101
AND MORE SEVERE MYALGIAS.
SHE DENIED SOB. I WENT WITH
THE MOBILE TEAM TO HER
HOME TO ASSESS HER ON 9/24.
AT THAT TIME, SHE REPORTED
THAT SHE CARES FOR HER
ELDERLY PARENTS, AND SAW
ONE OF HER BROTHERS WHO
RECENTLY RETURNED FROM
MEXICO WITH AN ILLNESS. NO
ONE ELSE WAS SICK. HER
SYMPTOMS BEGAN ON 9/22,
AND HAD WORSENER BY
TODAY, BUT AFTER I SPOKE TO

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Feb 2021 03:46:59

Generated On: 11 Aug 2021 22:51:43

HER BY PHONE, SHE TOOK
TYLENOL WITH SOME RELEIF
OF HER FEVER AND
MYALGIAS. ON MY EXAM
THAT DAY, SHE WAS IN NO
DISTRESS, TEMP 98.0, PULSE OX
100%, PULSE 84. HER LUNGS
WERE CLEAR ON EXAM. I
ADVISED HER TO CONTINUE
TYLENOL EVERY 4-6 HOURS
PRN. THE NP COLLECTED
ANOTHER NP SWAB FOR
LOCAL PROCESSING FOR
COVID19, AND ANOTHER FOR
RESPIRATORY VIRUS PANEL.
I AGAIN CALLED HER ON 9/26
AND SHE REPORTED THAT IN
THE PRECEDING 24 HOURS, SHE
WAS FEELING BETTER, BUT
DID DEVELOP ANOSMIA AND
AGEUSIA. SHE ALSO REPORTED
THAT NOW HER HUSBAND HAD
SYMPTOMS OF FEVER AND
MYALGIAS.

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 03:46:59

Generated On: 11 Aug 2021 22:51:43

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 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	FEVER, MYALGIAS AND HEADACHE
Dose per administration	1000
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

Name of Medication PSEUDOEPHEDRINE, 30MG X 1

Prophylaxis Yes ☐
No ☒

Indication SINUS CONGESTION FROM
COVID-19 INFECTION

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

	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)		1 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)		1 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 (3)

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 2000

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 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

Name of Medication ZINC

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

Name of Medication MULTIVITAMINS

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication COIVD-19 (CONFIRMED) -
MYALGIAS, FEVER

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

Name of Medication HYDROCODONE AND ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication MYALGIAS

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

401 of 2317

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

	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)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

Name of Medication COLESEVELAM

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 1250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

403 of 2317

EAB) (1725)

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Mar 2021 01:44:13

Generated On: 11 Aug 2021 22:51:43

	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)	23 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3492117

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 03:46:59

Generated On: 11 Aug 2021 22:51:43

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3492117

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:51:43

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

Case Report Form

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

US3492117

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:51:43

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

US3492117

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 15 Feb 2021 03:47:00

Generated On: 11 Aug 2021 22:51:43

Date of dosing discontinuation (dd MMM yyyy) 26 SEP 2020

Primary reason for dosing discontinuation

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

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

US3492117

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

SAEID	USA-US101-2020-MRNA-1273-P301000001
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)	2

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

SAEID	USA-US101-2020-MRNA-1273-P301000001
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)	2
Date of submission (Pre-filled from custom function)	28/SEP/2020 14:32
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

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Feb 2021 03:47:01

Generated On: 11 Aug 2021 22:51:43

SAEID	USA-US101-2020-MRNA-1273-P301000001
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)	2
Date of submission (Pre-filled from custom function)	02/NOV/2020 18:55
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

US3492117 (Prod: UIC Project WISH CRS)

US3492117

Form: Participant Creation

Generated On: 11 Aug 2021 22:51:43

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'US3492117'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:45:09

US3492117

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	10 Sep 2020 19:23:14

US3492117

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '10 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:45:10

US3492117

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[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 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Clinic (Clinic)'	Nusirat Williams (b) (4)	10 Sep 2020 19:23:14

US3492117

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered 'SCRN'	System	10 Sep 2020 19:23:14

US3492117

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered (b) (6) 1959'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:45:11

US3492117

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '61'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered 'YEARS'	System	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered '61'	System	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Female (F)'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'I'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Hispanic'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '10 Sep 2020'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered 'Sep 2020'	System	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered '2020'	System	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Amendment 2 (2)'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Nusirat Williams (b) (4)	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:45:10

US3492117

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered 'I'	System	10 Sep 2020 19:24:29

US3492117

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:29

US3492117

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:51:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)' reason for change: Per Query Resolution	Gizelle Alvarez (b) (4)	14 Oct 2020 19:14:39
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:46

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 19:16:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 19:16:30
Data point term sent to Coder	System	14 Oct 2020 19:15:33
User entered 'Post menopausal'	Gizelle Alvarez (b) (4)	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'un UNK 2007'	Gizelle Alvarez (b) (4)	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Gizelle Alvarez (b) (4)	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Gizelle Alvarez (b) (4)	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Gizelle Alvarez (b) (4)	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered 'Jan 2007'	System	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered '2007'	System	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered empty.	System	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered empty.	System	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	07 Jan 2021 15:00:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Jan 2021 15:00:41
Data point term sent to Coder	System	07 Jan 2021 14:44:38
User entered 'Hyperlipidemia'	Ian Feather (b) (4)	07 Jan 2021 14:44:17

US3492117

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered 'UN UNK 2016' reason for change: Data Entry Error	System	07 Jan 2021 14:44:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Ian Feather (b) (4)	07 Jan 2021 14:44:40
User entered ' 2016' (non-conformant).	(b) (4)	
	System	07 Jan 2021 14:44:17
	Ian Feather (b) (4)	07 Jan 2021 14:44:17
	(b) (4)	

US3492117

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Ian Feather (b) (4)	07 Jan 2021 14:44:17

US3492117

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Ian Feather (b) (4)	07 Jan 2021 14:44:17

US3492117

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Ian Feather (b) (4)	07 Jan 2021 14:44:17

US3492117

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Ian Feather (b) (4)	07 Jan 2021 14:44:17

US3492117

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered 'Jan 2016'	System	07 Jan 2021 14:44:40
User entered empty.	System	07 Jan 2021 14:44:17

US3492117

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered '2016'	System	07 Jan 2021 14:44:40
User entered empty.	System	07 Jan 2021 14:44:17

US3492117

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered empty.	System	07 Jan 2021 14:44:17

US3492117

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered empty.	System	07 Jan 2021 14:44:17

US3492117

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 17:05:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 17:05:40
Data point term sent to Coder	System	18 Mar 2021 17:04:29
User entered 'Dermal Filler Injection'	(b) (4), (b) (6)	18 Mar 2021 17:03:34

US3492117

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered 'Un UNK 2018'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:03:34

US3492117

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:03:34

US3492117

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:03:34

US3492117

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered 'Un UNK 2019'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:03:34

US3492117

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:03:34

US3492117

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered 'Jan 2018'	System	18 Mar 2021 17:03:34

US3492117

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered '2018'	System	18 Mar 2021 17:03:34

US3492117

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered 'Jan 2019'	System	18 Mar 2021 17:03:34

US3492117

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered '2019'	System	18 Mar 2021 17:03:34

US3492117

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Skin cosmetic procedure, LLT: Skin cosmetic procedure - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 17:05:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 17:05:40
Data point term sent to Coder	System	18 Mar 2021 17:04:29
User entered 'Skin Cosmetic Procedure'	(b) (4), (b) (6)	18 Mar 2021 17:04:04

US3492117

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered 'Un UNK 2018'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:04:04

US3492117

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:04:04

US3492117

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:04:04

US3492117

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered 'Un UNK 2019'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:04:04

US3492117

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:04:04

US3492117

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered 'Jan 2018'	System	18 Mar 2021 17:04:04

US3492117

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered '2018'	System	18 Mar 2021 17:04:04

US3492117

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered 'Jan 2019'	System	18 Mar 2021 17:04:04

US3492117

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered '2019'	System	18 Mar 2021 17:04:04

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '10 Sep 2020'	Nusirat Williams (b) (4)	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '13:50'	Nusirat Williams (b) (4)	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered '10 Sep 2020 13:50'	System	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '147' cm	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:25:45
DataPoint set to visible.	(b) (4) System	10 Sep 2020 19:24:29

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '52.9' kg	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:25:45
DataPoint set to visible.	(b) (4) System	10 Sep 2020 19:24:29

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered '24.48054'	System	10 Sep 2020 19:25:45
DataPoint set to visible.	System	10 Sep 2020 19:24:29

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered 'kg/m2'	System	10 Sep 2020 19:25:45
DataPoint set to visible.	System	10 Sep 2020 19:24:29

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User closed query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 13:42:41
Query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' answered with '-----corrected-----' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 19:58:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 19:58:46
User opened query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 16:39:58
User entered 'Other (Other)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered 'bpm'	System	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered 'breaths/min'	System	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered 'mmHg'	System	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User entered 'mmHg'	System	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17

US3492117

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	10 Sep 2020 19:26:00

US3492117

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '10 Sep 2020'	Nusirat Williams (b) (4)	10 Sep 2020 19:26:00

US3492117

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '10 Sep 2020'	Nusirat Williams (b) (4)	10 Sep 2020 19:28:20

US3492117

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:43

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:28:20

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:43

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 09:07:42
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. answered with 'Recorded in MH.' (Site from DM).	Gizelle Alvarez (b) (4) (b) (4)	14 Oct 2020 19:14:30
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:15:12
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:28:20

US3492117

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:43

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:28:20

US3492117

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:43

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Nusirat Williams (b) (4)	10 Sep 2020 19:28:20

US3492117

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:43

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Nusirat Williams (b) (4)	10 Sep 2020 19:28:20

US3492117

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:43

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'UN UNK 2007'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:28:20

US3492117

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:43

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Nusirat Williams (b) (4)	10 Sep 2020 19:28:20

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

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 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

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 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

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 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

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 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

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 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

[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 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

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 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

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 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

[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 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

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 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

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 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Not employed'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

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 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

[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 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'I'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

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 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:43:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:47

US3492117

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '10 Sep 2020'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:29:47

US3492117

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Clinic (Clinic)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:29:47

US3492117

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'VISIT1'	System	10 Sep 2020 19:29:47

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '10 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 19:10:00

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '112999'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 19:10:00

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 19:10:00

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:30:46

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:30:46

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:30:46

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:30:46

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:30:46

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 05:18:31
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	22 Nov 2020 20:03:00
User entered 'No (N)'	Andrea Wendrow (b) (4)	22 Nov 2020 20:02:40
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 20:27:05
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:09:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:03:18

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
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)	23 Oct 2020 08:17:11
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 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	19 Oct 2020 15:50:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	19 Oct 2020 15:50:34
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)	19 Oct 2020 12:50:16
User entered '147' cm	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 15:50:34
User entered '52.9' kg	Marla Schwarber (b) (4)	10 Sep 2020 19:32:11
	Nusirat Williams (b) (4)	
	(b) (4)	

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
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)	23 Oct 2020 08:17:11
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 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	19 Oct 2020 15:50:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	19 Oct 2020 15:50:34
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)	19 Oct 2020 12:50:16
User entered '147' cm	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 15:50:34
User entered '52.9' kg	Marla Schwarber (b) (4)	10 Sep 2020 19:32:11
	(b) (4)	

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User accepted default value 'Pre-Dose (PREDOSE)'	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11
	(b) (4)	

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '10 Sep 2020'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '13:50'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered '10 Sep 2020 13:50'	System	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '99' F	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Other (Other)'	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Ear'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '70'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'bpm'	System	10 Sep 2020 19:32:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '16'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'breaths/min'	System	10 Sep 2020 19:32:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '142'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'mmHg'	System	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '92'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'mmHg'	System	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
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)	23 Oct 2020 08:17:11
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 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	19 Oct 2020 15:50:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	19 Oct 2020 15:50:34
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)	19 Oct 2020 12:50:16
User entered '147' cm	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 15:50:34
User entered '52.9' kg	Marla Schwarber (b) (4)	10 Sep 2020 19:32:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User accepted default value 'Post-Dose (POSTDOSE)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
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	10 Sep 2020 20:00:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Nusirat Williams (b) (4)	10 Sep 2020 20:00:48
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Sep 2020 19:32:11
	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Nusirat Williams (b) (4)	10 Sep 2020 20:00:48
User entered empty.	(b) (4)	
	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '14:55' reason for change: Data Entry Error	(b) (4)	
	Nusirat Williams (b) (4)	10 Sep 2020 20:00:48
User entered empty.	(b) (4)	
	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered '10 Sep 2020 14:55'	System	10 Sep 2020 20:00:48
User entered empty.	System	10 Sep 2020 19:32:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '36.5' C reason for change: Data Entry Error	(b) (4)	
	Nusirat Williams (b) (4)	10 Sep 2020 20:00:48
User entered empty.	(b) (4)	
	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	
	Nusirat Williams (b) (4)	10 Sep 2020 20:00:48
User entered empty.	(b) (4)	
	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Ear' reason for change: Data Entry Error	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 20:00:48
User entered empty.	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '63' reason for change: Data Entry Error	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 20:00:48
User entered empty.	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'bpm'	System	10 Sep 2020 20:00:48
User entered empty.	System	10 Sep 2020 19:32:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '18' reason for change: Data Entry Error	(b) (4)	
	Nusirat Williams (b) (4)	10 Sep 2020 20:00:48
User entered empty.	(b) (4)	
	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'breaths/min'	System	10 Sep 2020 20:00:48
User entered empty.	System	10 Sep 2020 19:32:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User closed query 'Per CDM, Please advise if the value is CS/NCS. If CS, please report AE as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 09:55:40
Query 'Per CDM, Please advise if the value is CS/NCS. If CS, please report AE as appropriate. ' answered with 'NCS' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	11 Sep 2020 16:54:04
User opened query 'Per CDM, Please advise if the value is CS/NCS. If CS, please report AE as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 13:18:08
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 13:17:12
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Data correct, there is no defined BP range in protocol' (Site from System).	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 20:02:44
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	10 Sep 2020 20:00:48
User entered '165' reason for change: Data Entry Error	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 20:00:48
User entered empty.	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'mmHg'	System	10 Sep 2020 20:00:48
User entered empty.	System	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '92' reason for change: Data Entry Error	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 20:00:48
User entered empty.	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'mmHg'	System	10 Sep 2020 20:00:48
User entered empty.	System	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:32:20

US3492117

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '10 Sep 2020'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:32:20

US3492117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:59:02

US3492117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:59:02

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:59:02

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 19:59:02

US3492117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '10 Sep 2020'	Nusirat Williams (b) (4)	10 Sep 2020 19:59:02

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '14:48'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:59:02

US3492117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered '10 Sep 2020 14:48'	System	10 Sep 2020 19:59:02

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Left Arm (LEFT ARM)'	Nusirat Williams (b) (4)	10 Sep 2020 19:59:02

US3492117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'ONCE'	System	10 Sep 2020 19:59:02

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 19:59:02

US3492117

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	10 Sep 2020 19:45:39

US3492117

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '10 Sep 2020'	Gizelle Alvarez (b) (4)	10 Sep 2020 19:45:39

US3492117

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '14:15'	Gizelle Alvarez (b) (4)	10 Sep 2020 19:45:39

US3492117

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered '10 Sep 2020 14:15'	System	10 Sep 2020 19:45:39

US3492117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:51:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '10 Sep 2020'	Gizelle Alvarez (b) (4)	10 Sep 2020 19:45:52

US3492117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Gizelle Alvarez (b) (4)	10 Sep 2020 19:45:52

US3492117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	10 Sep 2020 19:45:52

US3492117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '14:30'	Gizelle Alvarez (b) (4)	10 Sep 2020 19:45:52

US3492117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered '10 Sep 2020 14:30'	System	10 Sep 2020 19:45:52

US3492117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Gizelle Alvarez (b) (4)	10 Sep 2020 19:45:52

US3492117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	Gizelle Alvarez (b) (4)	10 Sep 2020 19:45:52

US3492117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Gizelle Alvarez (b) (4)	10 Sep 2020 19:45:52

US3492117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered empty.	System	10 Sep 2020 19:45:52

US3492117

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	10 Sep 2020 19:32:38

US3492117

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'I'	System	10 Sep 2020 19:32:38

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:10:44', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '645baac8-a814-486b-b255-1b467e9119a6' User entered 'Yes (Y)'	System	10 Sep 2020 20:11:18
	System	10 Sep 2020 20:11:18

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:11:04', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '645baac8-a814-486b-b255-1b467e9119a6' User entered '97.8'	System	10 Sep 2020 20:11:18
	System	10 Sep 2020 20:11:18

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:11:10', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '645baac8-a814-486b-b255-1b467e9119a6'	System	10 Sep 2020 20:11:18
User entered 'No (N)'	System	10 Sep 2020 20:11:18

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:11:16', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '645baac8-a814-486b-b255-1b467e9119a6' User entered '10 Sep 2020 15:11'	System	10 Sep 2020 20:11:18
	System	10 Sep 2020 20:11:18

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '10 Sep 2020 15:08'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '10 Sep 2020 17:38'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:11:29', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f5118b8e-91a5-40a5-9cc8-ccaffa4da664' User entered 'Yes (Y)'	System	11 Sep 2020 14:12:01
	System	11 Sep 2020 14:12:01

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:11:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f5118b8e-91a5-40a5-9cc8-ccaffa4da664' User entered '98.1'	System	11 Sep 2020 14:12:01
	System	11 Sep 2020 14:12:01

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:11:46', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f5118b8e-91a5-40a5-9cc8-ccaffa4da664'	System	11 Sep 2020 14:12:01
User entered 'No (N)'	System	11 Sep 2020 14:12:01

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:11:56', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f5118b8e-91a5-40a5-9cc8-ccaffa4da664' User entered '11 Sep 2020 09:11'	System	11 Sep 2020 14:12:01
	System	11 Sep 2020 14:12:01

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '10 Sep 2020 18:33'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 2'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:51:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:11:17', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'ecd30c09-1b5e-4c36-aacb-cfb4df00c88e' User entered 'Yes (Y)'	System	12 Sep 2020 13:11:47
	System	12 Sep 2020 13:11:47

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:51:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:11:26', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'ecd30c09-1b5e-4c36-aacb-cfb4df00c88e' User entered '98.2'	System	12 Sep 2020 13:11:47
	System	12 Sep 2020 13:11:47

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:11:32', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'ecd30c09-1b5e-4c36-aacb-cfb4df00c88e' User entered 'No (N)'	System	12 Sep 2020 13:11:47
	System	12 Sep 2020 13:11:47

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:11:41', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'ecd30c09-1b5e-4c36-aacb-cfb4df00c88e' User entered '12 Sep 2020 08:11'	System	12 Sep 2020 13:11:47
	System	12 Sep 2020 13:11:47

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 3'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:51:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:34:51', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'dcbc92d6-0819-4996-857d-1206f940bb7b' User entered 'Yes (Y)'	System	13 Sep 2020 13:35:15
	System	13 Sep 2020 13:35:15

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:51:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:35:01', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'dcbc92d6-0819-4996-857d-1206f940bb7b' User entered '97.5'	System	13 Sep 2020 13:35:15
	System	13 Sep 2020 13:35:15

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:35:05', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'dcbc92d6-0819-4996-857d-1206f940bb7b' User entered 'No (N)'	System	13 Sep 2020 13:35:15
	System	13 Sep 2020 13:35:15

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:35:13', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'dcbc92d6-0819-4996-857d-1206f940bb7b' User entered '13 Sep 2020 08:35'	System	13 Sep 2020 13:35:15
	System	13 Sep 2020 13:35:15

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 4'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:51:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:25:49', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '65783dde-e242-4ce9-8bbf-d4b797603401' User entered 'Yes (Y)'	System	14 Sep 2020 13:26:13
	System	14 Sep 2020 13:26:13

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:51:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:25:58', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '65783dde-e242-4ce9-8bbf-d4b797603401' User entered '96.8'	System	14 Sep 2020 13:26:13
	System	14 Sep 2020 13:26:13

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:26:06', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '65783dde-e242-4ce9-8bbf-d4b797603401' User entered 'No (N)'	System	14 Sep 2020 13:26:13
	System	14 Sep 2020 13:26:13

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:26:10', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '65783dde-e242-4ce9-8bbf-d4b797603401' User entered '14 Sep 2020 08:26'	System	14 Sep 2020 13:26:13
	System	14 Sep 2020 13:26:13

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 5'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:51:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:40:11', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9c1afe3b-c80c-4707-aa60-6a6f1d023867' User entered 'Yes (Y)'	System	15 Sep 2020 12:40:31
	System	15 Sep 2020 12:40:31

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:51:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:40:18', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9c1afe3b-c80c-4707-aa60-6a6f1d023867' User entered '97.9'	System	15 Sep 2020 12:40:31
	System	15 Sep 2020 12:40:31

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:40:26', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9c1afe3b-c80c-4707-aa60-6a6f1d023867'	System	15 Sep 2020 12:40:31
User entered 'No (N)'	System	15 Sep 2020 12:40:31

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:40:30', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9c1afe3b-c80c-4707-aa60-6a6f1d023867' User entered '15 Sep 2020 07:40'	System	15 Sep 2020 12:40:31
	System	15 Sep 2020 12:40:31

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 6'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:51:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:41:01', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '2e87f36a-837e-474c-9c0e-40d6ad4d8171' User entered 'Yes (Y)'	System	16 Sep 2020 13:41:19
	System	16 Sep 2020 13:41:19

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:51:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:41:07', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '2e87f36a-837e-474c-9c0e-40d6ad4d8171' User entered '98.2'	System	16 Sep 2020 13:41:19
	System	16 Sep 2020 13:41:19

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:41:15', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '2e87f36a-837e-474c-9c0e-40d6ad4d8171' User entered 'No (N)'	System	16 Sep 2020 13:41:19
	System	16 Sep 2020 13:41:19

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:41:18', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '2e87f36a-837e-474c-9c0e-40d6ad4d8171' User entered '16 Sep 2020 08:41'	System	16 Sep 2020 13:41:19
	System	16 Sep 2020 13:41:19

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 7'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:51:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T09:59:50', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'a364f1cf-517c-40d3-b6b0-e5aaf452b8ec' User entered 'Yes (Y)'	System	17 Sep 2020 15:00:09
	System	17 Sep 2020 15:00:09

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:51:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T09:59:55', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'a364f1cf-517c-40d3-b6b0-e5aaf452b8ec' User entered '98.1'	System	17 Sep 2020 15:00:09
	System	17 Sep 2020 15:00:09

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T10:00:02', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'a364f1cf-517c-40d3-b6b0-e5aaf452b8ec'	System	17 Sep 2020 15:00:09
User entered 'No (N)'	System	17 Sep 2020 15:00:09

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T10:00:05', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'a364f1cf-517c-40d3-b6b0-e5aaf452b8ec' User entered '17 Sep 2020 10:00'	System	17 Sep 2020 15:00:09
	System	17 Sep 2020 15:00:09

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:11:24', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '131ac0ce-7b95-4322-99ab-4fb82957491d' User entered 'None (1)'	System	10 Sep 2020 20:11:57
	System	10 Sep 2020 20:11:57

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:11:37', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '131ac0ce-7b95-4322-99ab-4fb82957491d' User entered 'No (N)'	System	10 Sep 2020 20:11:57
	System	10 Sep 2020 20:11:57

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:11:43', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '131ac0ce-7b95-4322-99ab-4fb82957491d' User entered 'No (N)'	System	10 Sep 2020 20:11:57
	System	10 Sep 2020 20:11:57

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:11:49', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '131ac0ce-7b95-4322-99ab-4fb82957491d' User entered 'None (1)'	System	10 Sep 2020 20:11:57
	System	10 Sep 2020 20:11:57

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:11:53', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '131ac0ce-7b95-4322-99ab-4fb82957491d' User entered '10 Sep 2020 15:11'	System	10 Sep 2020 20:11:57
	System	10 Sep 2020 20:11:57

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '10 Sep 2020 15:08'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '10 Sep 2020 17:38'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:12:08', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '5021a868-cf59-4161-bb81-7b7570faf90d'	System	11 Sep 2020 14:13:22
User entered 'None (1)'	System	11 Sep 2020 14:13:22

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:12:35', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '5021a868-cf59-4161-bb81-7b7570faf90d' User entered 'No (N)'	System	11 Sep 2020 14:13:22
	System	11 Sep 2020 14:13:22

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:12:40', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '5021a868-cf59-4161-bb81-7b7570faf90d' User entered 'No (N)'	System	11 Sep 2020 14:13:22
	System	11 Sep 2020 14:13:22

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:13:14', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '5021a868-cf59-4161-bb81-7b7570faf90d'	System	11 Sep 2020 14:13:22
User entered 'None (1)'	System	11 Sep 2020 14:13:22

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:13:20', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '5021a868-cf59-4161-bb81-7b7570faf90d' User entered '11 Sep 2020 09:13'	System	11 Sep 2020 14:13:22
	System	11 Sep 2020 14:13:22

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '10 Sep 2020 18:33'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 2'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:11:45', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '35f63309-6524-4132-b14f-c02e21f652b1' User entered 'None (1)'	System	12 Sep 2020 13:12:17
	System	12 Sep 2020 13:12:17

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:11:52', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '35f63309-6524-4132-b14f-c02e21f652b1' User entered 'No (N)'	System	12 Sep 2020 13:12:17
	System	12 Sep 2020 13:12:17

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:11:58', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '35f63309-6524-4132-b14f-c02e21f652b1' User entered 'No (N)'	System	12 Sep 2020 13:12:17
	System	12 Sep 2020 13:12:17

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:12:12', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '35f63309-6524-4132-b14f-c02e21f652b1' User entered 'None (1)'	System	12 Sep 2020 13:12:17
	System	12 Sep 2020 13:12:17

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:12:16', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '35f63309-6524-4132-b14f-c02e21f652b1' User entered '12 Sep 2020 08:12'	System	12 Sep 2020 13:12:17
	System	12 Sep 2020 13:12:17

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 3'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:35:17', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'c0540025-ce27-4687-a0e5-8dcb922b24db' User entered 'None (1)'	System	13 Sep 2020 13:35:45
	System	13 Sep 2020 13:35:45

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:35:20', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'c0540025-ce27-4687-a0e5-8dcb922b24db' User entered 'No (N)'	System	13 Sep 2020 13:35:45
	System	13 Sep 2020 13:35:45

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:35:24', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'c0540025-ce27-4687-a0e5-8dcb922b24db' User entered 'No (N)'	System	13 Sep 2020 13:35:45
	System	13 Sep 2020 13:35:45

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:35:38', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'c0540025-ce27-4687-a0e5-8dcb922b24db' User entered 'None (1)'	System	13 Sep 2020 13:35:45
	System	13 Sep 2020 13:35:45

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:35:42', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'c0540025-ce27-4687-a0e5-8dc922b24db' User entered '13 Sep 2020 08:35'	System	13 Sep 2020 13:35:45
	System	13 Sep 2020 13:35:45

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 4'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:26:18', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f77908cf-234f-4695-890e-a587032d5ed3'	System	14 Sep 2020 13:26:40
User entered 'None (1)'	System	14 Sep 2020 13:26:40

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:26:22', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f77908cf-234f-4695-890e-a587032d5ed3' User entered 'No (N)'	System	14 Sep 2020 13:26:40
	System	14 Sep 2020 13:26:40

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:26:25', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f77908cf-234f-4695-890e-a587032d5ed3' User entered 'No (N)'	System	14 Sep 2020 13:26:40
	System	14 Sep 2020 13:26:40

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:26:36', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f77908cf-234f-4695-890e-a587032d5ed3'	System	14 Sep 2020 13:26:40
User entered 'None (1)'	System	14 Sep 2020 13:26:40

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:26:38', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f77908cf-234f-4695-890e-a587032d5ed3' User entered '14 Sep 2020 08:26'	System	14 Sep 2020 13:26:40
	System	14 Sep 2020 13:26:40

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 5'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:40:47', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'c7762c37-cb42-4db0-8fff-73d56c36cb37'	System	15 Sep 2020 12:41:03
User entered 'None (1)'	System	15 Sep 2020 12:41:03

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:40:49', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'c7762c37-cb42-4db0-8fff-73d56c36cb37'	System	15 Sep 2020 12:41:03
User entered 'No (N)'	System	15 Sep 2020 12:41:03

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:40:52', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'c7762c37-cb42-4db0-8fff-73d56c36cb37'	System	15 Sep 2020 12:41:03
User entered 'No (N)'	System	15 Sep 2020 12:41:03

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:40:56', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'c7762c37-cb42-4db0-8fff-73d56c36cb37'	System	15 Sep 2020 12:41:03
User entered 'None (1)'	System	15 Sep 2020 12:41:03

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:40:58', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'c7762c37-cb42-4db0-8fff-73d56c36cb37'	System	15 Sep 2020 12:41:03
User entered '15 Sep 2020 07:40'	System	15 Sep 2020 12:41:03

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 6'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:41:22', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '1438fbad-eb3e-4a29-ad50-e78372c361f3'	System	16 Sep 2020 13:41:49
User entered 'None (1)'	System	16 Sep 2020 13:41:49

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:41:34', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '1438fbad-eb3e-4a29-ad50-e78372c361f3' User entered 'No (N)'	System	16 Sep 2020 13:41:49
	System	16 Sep 2020 13:41:49

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:41:38', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '1438fbad-eb3e-4a29-ad50-e78372c361f3' User entered 'No (N)'	System	16 Sep 2020 13:41:49
	System	16 Sep 2020 13:41:49

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:41:44', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '1438fbad-eb3e-4a29-ad50-e78372c361f3' User entered 'None (1)'	System	16 Sep 2020 13:41:49
	System	16 Sep 2020 13:41:49

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:41:47', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '1438fbad-eb3e-4a29-ad50-e78372c361f3' User entered '16 Sep 2020 08:41'	System	16 Sep 2020 13:41:49
	System	16 Sep 2020 13:41:49

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 7'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T10:00:10', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f750f7a6-4350-46eb-b8d5-fcbe009b8416'	System	17 Sep 2020 15:00:27
User entered 'None (1)'	System	17 Sep 2020 15:00:27

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T10:00:13', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f750f7a6-4350-46eb-b8d5-fcbe009b8416' User entered 'No (N)'	System	17 Sep 2020 15:00:27
	System	17 Sep 2020 15:00:27

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T10:00:17', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f750f7a6-4350-46eb-b8d5-fcbe009b8416' User entered 'No (N)'	System	17 Sep 2020 15:00:27
	System	17 Sep 2020 15:00:27

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T10:00:21', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f750f7a6-4350-46eb-b8d5-fcbe009b8416' User entered 'None (1)'	System	17 Sep 2020 15:00:27
	System	17 Sep 2020 15:00:27

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T10:00:24', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f750f7a6-4350-46eb-b8d5-fcbe009b8416' User entered '17 Sep 2020 10:00'	System	17 Sep 2020 15:00:27
	System	17 Sep 2020 15:00:27

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:12:02', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'cccc3052-30c1-4bf4-821d-fdb9cb9eea9a' User entered 'None (0)'	System	10 Sep 2020 20:12:35
	System	10 Sep 2020 20:12:35

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:12:07', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'cccc3052-30c1-4bf4-821d-fdb9cb9eea9a' User entered 'None (0)'	System	10 Sep 2020 20:12:35
	System	10 Sep 2020 20:12:35

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:12:11', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'cccc3052-30c1-4bf4-821d-fdb9cb9eea9a' User entered 'None (0)'	System	10 Sep 2020 20:12:35
	System	10 Sep 2020 20:12:35

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:12:15', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'cccc3052-30c1-4bf4-821d-fdb9cb9eea9a' User entered 'None (0)'	System	10 Sep 2020 20:12:35
	System	10 Sep 2020 20:12:35

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:12:20', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'cccc3052-30c1-4bf4-821d-fdb9cb9eea9a' User entered 'None (0)'	System	10 Sep 2020 20:12:35
	System	10 Sep 2020 20:12:35

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:12:23', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'cccc3052-30c1-4bf4-821d-fdb9cb9eea9a' User entered 'None (0)'	System	10 Sep 2020 20:12:35
	System	10 Sep 2020 20:12:35

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:12:30', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'cccc3052-30c1-4bf4-821d-fdb9cb9eea9a' User entered 'No (N)'	System	10 Sep 2020 20:12:35
	System	10 Sep 2020 20:12:35

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-10T15:12:33', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'cccc3052-30c1-4bf4-821d-fdb9cb9eea9a' User entered '10 Sep 2020 15:12'	System	10 Sep 2020 20:12:35
	System	10 Sep 2020 20:12:35

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '10 Sep 2020 15:08'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '10 Sep 2020 17:38'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:13:47', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '2a0c3af1-b3a0-4b97-9d4b-6414c09d184e' User entered 'None (0)'	System	11 Sep 2020 14:14:41
	System	11 Sep 2020 14:14:41

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:13:55', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '2a0c3af1-b3a0-4b97-9d4b-6414c09d184e' User entered 'None (0)'	System	11 Sep 2020 14:14:41
	System	11 Sep 2020 14:14:41

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:13:59', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '2a0c3af1-b3a0-4b97-9d4b-6414c09d184e' User entered 'None (0)'	System	11 Sep 2020 14:14:41
	System	11 Sep 2020 14:14:41

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:14:07', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '2a0c3af1-b3a0-4b97-9d4b-6414c09d184e' User entered 'None (0)'	System	11 Sep 2020 14:14:41
	System	11 Sep 2020 14:14:41

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:14:10', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '2a0c3af1-b3a0-4b97-9d4b-6414c09d184e' User entered 'None (0)'	System	11 Sep 2020 14:14:41
	System	11 Sep 2020 14:14:41

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:14:14', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '2a0c3af1-b3a0-4b97-9d4b-6414c09d184e' User entered 'None (0)'	System	11 Sep 2020 14:14:41
	System	11 Sep 2020 14:14:41

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:14:23', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '2a0c3af1-b3a0-4b97-9d4b-6414c09d184e' User entered 'No (N)'	System	11 Sep 2020 14:14:41
	System	11 Sep 2020 14:14:41

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-11T09:14:29', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '2a0c3af1-b3a0-4b97-9d4b-6414c09d184e' User entered '11 Sep 2020 09:14'	System	11 Sep 2020 14:14:41
	System	11 Sep 2020 14:14:41

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '10 Sep 2020 18:33'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 2'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:12:27', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '22dc8dbf-b47c-4bcf-9120-03ae4c607c15' User entered 'None (0)'	System	12 Sep 2020 13:14:28
	System	12 Sep 2020 13:14:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:12:43', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '22dc8dbf-b47c-4bcf-9120-03ae4c607c15' User entered 'None (0)'	System	12 Sep 2020 13:14:28
	System	12 Sep 2020 13:14:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:13:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '22dc8dbf-b47c-4bcf-9120-03ae4c607c15' User entered 'None (0)'	System	12 Sep 2020 13:14:28
	System	12 Sep 2020 13:14:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:13:12', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '22dc8dbf-b47c-4bcf-9120-03ae4c607c15' User entered 'None (0)'	System	12 Sep 2020 13:14:28
	System	12 Sep 2020 13:14:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:13:21', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '22dc8dbf-b47c-4bcf-9120-03ae4c607c15' User entered 'None (0)'	System	12 Sep 2020 13:14:28
	System	12 Sep 2020 13:14:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:13:29', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '22dc8dbf-b47c-4bcf-9120-03ae4c607c15' User entered 'None (0)'	System	12 Sep 2020 13:14:28
	System	12 Sep 2020 13:14:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:13:38', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '22dc8dbf-b47c-4bcf-9120-03ae4c607c15' User entered 'No (N)'	System	12 Sep 2020 13:14:28
	System	12 Sep 2020 13:14:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-12T08:13:41', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '22dc8dbf-b47c-4bcf-9120-03ae4c607c15' User entered '12 Sep 2020 08:13'	System	12 Sep 2020 13:14:28
	System	12 Sep 2020 13:14:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 3'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:35:48', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '5d1cc57e-5cbc-4f70-99fe-56073416703c' User entered 'None (0)'	System	13 Sep 2020 13:36:13
	System	13 Sep 2020 13:36:13

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:35:50', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '5d1cc57e-5cbc-4f70-99fe-56073416703c' User entered 'None (0)'	System	13 Sep 2020 13:36:13
	System	13 Sep 2020 13:36:13

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:35:55', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '5d1cc57e-5cbc-4f70-99fe-56073416703c' User entered 'None (0)'	System	13 Sep 2020 13:36:13
	System	13 Sep 2020 13:36:13

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:35:57', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '5d1cc57e-5cbc-4f70-99fe-56073416703c' User entered 'None (0)'	System	13 Sep 2020 13:36:13
	System	13 Sep 2020 13:36:13

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:36:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '5d1cc57e-5cbc-4f70-99fe-56073416703c' User entered 'None (0)'	System	13 Sep 2020 13:36:13
	System	13 Sep 2020 13:36:13

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:36:02', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '5d1cc57e-5cbc-4f70-99fe-56073416703c' User entered 'None (0)'	System	13 Sep 2020 13:36:13
	System	13 Sep 2020 13:36:13

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:36:09', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '5d1cc57e-5cbc-4f70-99fe-56073416703c' User entered 'No (N)'	System	13 Sep 2020 13:36:13
	System	13 Sep 2020 13:36:13

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-13T08:36:11', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '5d1cc57e-5cbc-4f70-99fe-56073416703c' User entered '13 Sep 2020 08:36'	System	13 Sep 2020 13:36:13
	System	13 Sep 2020 13:36:13

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 4'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:26:43', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '4bff093b-c661-4826-820c-565b1cc9fcf4' User entered 'None (0)'	System	14 Sep 2020 13:27:18
	System	14 Sep 2020 13:27:18

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:26:46', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '4bff093b-c661-4826-820c-565b1cc9fcf4' User entered 'None (0)'	System	14 Sep 2020 13:27:18
	System	14 Sep 2020 13:27:18

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:26:50', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '4bff093b-c661-4826-820c-565b1cc9fcf4' User entered 'None (0)'	System	14 Sep 2020 13:27:18
	System	14 Sep 2020 13:27:18

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:26:58', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '4bff093b-c661-4826-820c-565b1cc9fcf4' User entered 'None (0)'	System	14 Sep 2020 13:27:18
	System	14 Sep 2020 13:27:18

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:27:02', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '4bff093b-c661-4826-820c-565b1cc9fcf4' User entered 'None (0)'	System	14 Sep 2020 13:27:18
	System	14 Sep 2020 13:27:18

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:27:05', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '4bff093b-c661-4826-820c-565b1cc9fcf4' User entered 'None (0)'	System	14 Sep 2020 13:27:18
	System	14 Sep 2020 13:27:18

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:27:11', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '4bff093b-c661-4826-820c-565b1cc9fcf4' User entered 'No (N)'	System	14 Sep 2020 13:27:18
	System	14 Sep 2020 13:27:18

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-14T08:27:14', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '4bff093b-c661-4826-820c-565b1cc9fcf4' User entered '14 Sep 2020 08:27'	System	14 Sep 2020 13:27:18
	System	14 Sep 2020 13:27:18

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 5'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:41:04', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '4389ebe0-4084-4fa2-bc6d-8490fd54ed6d' User entered 'None (0)'	System	15 Sep 2020 12:41:27
	System	15 Sep 2020 12:41:27

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:41:06', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '4389ebe0-4084-4fa2-bc6d-8490fd54ed6d' User entered 'None (0)'	System	15 Sep 2020 12:41:27
	System	15 Sep 2020 12:41:27

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:41:09', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '4389ebe0-4084-4fa2-bc6d-8490fd54ed6d' User entered 'None (0)'	System	15 Sep 2020 12:41:27
	System	15 Sep 2020 12:41:27

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:41:13', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '4389ebe0-4084-4fa2-bc6d-8490fd54ed6d' User entered 'None (0)'	System	15 Sep 2020 12:41:27
	System	15 Sep 2020 12:41:27

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:41:16', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '4389ebe0-4084-4fa2-bc6d-8490fd54ed6d' User entered 'None (0)'	System	15 Sep 2020 12:41:27
	System	15 Sep 2020 12:41:27

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:41:18', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '4389ebe0-4084-4fa2-bc6d-8490fd54ed6d' User entered 'None (0)'	System	15 Sep 2020 12:41:27
	System	15 Sep 2020 12:41:27

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:41:22', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '4389ebe0-4084-4fa2-bc6d-8490fd54ed6d' User entered 'No (N)'	System	15 Sep 2020 12:41:27
	System	15 Sep 2020 12:41:27

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-15T07:41:25', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '4389ebe0-4084-4fa2-bc6d-8490fd54ed6d' User entered '15 Sep 2020 07:41'	System	15 Sep 2020 12:41:27
	System	15 Sep 2020 12:41:27

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 6'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:41:52', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'b2e4feb9-963e-4556-b3cb-9adf90702445' User entered 'None (0)'	System	16 Sep 2020 13:42:28
	System	16 Sep 2020 13:42:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:41:54', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'b2e4feb9-963e-4556-b3cb-9adf90702445' User entered 'None (0)'	System	16 Sep 2020 13:42:28
	System	16 Sep 2020 13:42:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:41:58', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'b2e4feb9-963e-4556-b3cb-9adf90702445' User entered 'None (0)'	System	16 Sep 2020 13:42:28
	System	16 Sep 2020 13:42:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:42:04', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'b2e4feb9-963e-4556-b3cb-9adf90702445' User entered 'None (0)'	System	16 Sep 2020 13:42:28
	System	16 Sep 2020 13:42:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:42:07', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'b2e4feb9-963e-4556-b3cb-9adf90702445' User entered 'None (0)'	System	16 Sep 2020 13:42:28
	System	16 Sep 2020 13:42:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:42:10', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'b2e4feb9-963e-4556-b3cb-9adf90702445' User entered 'None (0)'	System	16 Sep 2020 13:42:28
	System	16 Sep 2020 13:42:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:42:23', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'b2e4feb9-963e-4556-b3cb-9adf90702445'	System	16 Sep 2020 13:42:28
User entered 'No (N)'	System	16 Sep 2020 13:42:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-16T08:42:26', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'b2e4feb9-963e-4556-b3cb-9adf90702445' User entered '16 Sep 2020 08:42'	System	16 Sep 2020 13:42:28
	System	16 Sep 2020 13:42:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 7'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T10:00:28', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '0bbb7e1b-3c2c-4f12-ab1d-90e9b7125635' User entered 'None (0)'	System	17 Sep 2020 15:00:55
	System	17 Sep 2020 15:00:55

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T10:00:31', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '0bbb7e1b-3c2c-4f12-ab1d-90e9b7125635' User entered 'None (0)'	System	17 Sep 2020 15:00:55
	System	17 Sep 2020 15:00:55

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T10:00:34', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '0bbb7e1b-3c2c-4f12-ab1d-90e9b7125635' User entered 'None (0)'	System	17 Sep 2020 15:00:55
	System	17 Sep 2020 15:00:55

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T10:00:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '0bbb7e1b-3c2c-4f12-ab1d-90e9b7125635' User entered 'None (0)'	System	17 Sep 2020 15:00:55
	System	17 Sep 2020 15:00:55

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T10:00:42', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '0bbb7e1b-3c2c-4f12-ab1d-90e9b7125635' User entered 'None (0)'	System	17 Sep 2020 15:00:55
	System	17 Sep 2020 15:00:55

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T10:00:44', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '0bbb7e1b-3c2c-4f12-ab1d-90e9b7125635' User entered 'None (0)'	System	17 Sep 2020 15:00:55
	System	17 Sep 2020 15:00:55

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

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 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T10:00:50', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '0bbb7e1b-3c2c-4f12-ab1d-90e9b7125635' User entered 'No (N)'	System	17 Sep 2020 15:00:55
	System	17 Sep 2020 15:00:55

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-09-17T10:00:53', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '0bbb7e1b-3c2c-4f12-ab1d-90e9b7125635' User entered '17 Sep 2020 10:00'	System	17 Sep 2020 15:00:55
	System	17 Sep 2020 15:00:55

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:59:02

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Addis Mekonnen (b) (4)	17 Sep 2020 22:19:04

US3492117

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '17 Sep 2020'	Addis Mekonnen (b) (4)	17 Sep 2020 22:19:04

US3492117

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Contact Made (CONTACT MADE)'	Addis Mekonnen (b) (4)	17 Sep 2020 22:19:04

US3492117

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	(b) (4) Addis Mekonnen (b) (4)	17 Sep 2020 22:19:04

US3492117

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Addis Mekonnen (b) (4)	17 Sep 2020 22:19:07

US3492117

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'I'	System	17 Sep 2020 22:19:07

US3492117

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Elena Llinas (b) (4)	24 Sep 2020 21:39:10

US3492117

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '24 Sep 2020'	Elena Llinas (b) (4)	24 Sep 2020 21:39:10

US3492117

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Contact Made (CONTACT MADE)'	Elena Llinas (b) (4)	24 Sep 2020 21:39:10

US3492117

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Elena Llinas (b) (4)	24 Sep 2020 21:39:10

US3492117

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Elena Llinas (b) (4)	24 Sep 2020 21:39:18

US3492117

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'I'	System	24 Sep 2020 21:39:18

US3492117

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 18:56:27

US3492117

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 18:56:27

US3492117

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 18:56:27

US3492117

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered 'subject in illness/convalescence'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 18:56:27

US3492117

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	08 Oct 2020 17:25:16

US3492117

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'I'	System	08 Oct 2020 17:25:16

US3492117

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	08 Oct 2020 17:25:36

US3492117

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '8 Oct 2020'	Nusirat Williams (b) (4)	08 Oct 2020 17:25:36

US3492117

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Clinic (Clinic)'	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:25:36

US3492117

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'VISIT2'	System	08 Oct 2020 17:25:36

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User accepted default value 'Pre-Dose (PREDOSE)'	Nusirat Williams (b) (4)	08 Oct 2020 17:26:29
	(b) (4)	

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '8 Oct 2020'	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '11:55'	Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered '8 Oct 2020 11:55'	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '98.7' F	Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Other (Other)'	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'tympanic'	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '71'	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'bpm'	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '12'	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'breaths/min'	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '123'	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'mmHg'	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '70'	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'mmHg'	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User accepted default value 'Post-Dose (POSTDOSE)'	Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered empty.	Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered empty.	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered empty.	Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered empty.	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered empty.	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered empty.	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered empty.	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	08 Oct 2020 17:26:37

US3492117

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '8 Oct 2020'	Nusirat Williams (b) (4)	08 Oct 2020 17:26:37

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	08 Oct 2020 17:27:02
User entered 'Confirmed COVID-19 (COVID)' reason for change: Data Entry Error	Nusirat Williams (b) (4)	08 Oct 2020 17:27:02
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	08 Oct 2020 17:26:48
User entered empty.	System	08 Oct 2020 17:26:48
	Nusirat Williams (b) (4)	08 Oct 2020 17:26:48
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered empty.	System	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered empty.	Nusirat Williams (b) (4)	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered empty.	System	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered empty.	System	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered empty.	System	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	08 Oct 2020 17:27:16

US3492117

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '8 Oct 2020'	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:27:16

US3492117

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '12:10'	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:27:16

US3492117

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered '8 Oct 2020 12:10'	System	08 Oct 2020 17:27:16

US3492117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:51:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '8 Oct 2020'	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:27:31

US3492117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nusirat Williams (b) (4)	08 Oct 2020 17:27:31

US3492117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	08 Oct 2020 17:27:31

US3492117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '12:15'	Nusirat Williams (b) (4)	08 Oct 2020 17:27:31

US3492117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered '8 Oct 2020 12:15'	System	08 Oct 2020 17:27:31

US3492117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nusirat Williams (b) (4)	08 Oct 2020 17:27:31

US3492117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'No (N)'	Nusirat Williams (b) (4)	08 Oct 2020 17:27:31

US3492117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:27:31

US3492117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered empty.	System	08 Oct 2020 17:27:31

US3492117

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	08 Oct 2020 17:27:36

US3492117

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'I'	System	08 Oct 2020 17:27:36

US3492117

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Diana Bahena (b) (4)	23 Oct 2020 15:16:30

US3492117

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '22 Oct 2020'	Diana Bahena (b) (4)	23 Oct 2020 15:16:30

US3492117

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Contact Made (CONTACT MADE)'	Diana Bahena (b) (4)	23 Oct 2020 15:16:30

US3492117

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	(b) (4) Diana Bahena (b) (4)	23 Oct 2020 15:16:30

US3492117

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	20 Oct 2020 17:16:45

US3492117

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'I'	System	20 Oct 2020 17:16:45

US3492117

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	02 Nov 2020 19:27:14
	(b) (4)	

US3492117

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '30 Oct 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:27:14

US3492117

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:27:14

US3492117

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:27:14

US3492117

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	20 Oct 2020 21:13:40

US3492117

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'I'	System	20 Oct 2020 21:13:40

US3492117

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 18:57:37

US3492117

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered empty.	Andrea Wendrow (b) (4)	25 Mar 2021 18:57:37

US3492117

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 18:57:37

US3492117

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 18:57:37

US3492117

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	20 Oct 2020 21:13:50

US3492117

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'I'	System	20 Oct 2020 21:13:50

US3492117

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:26:25

US3492117

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '6 Nov 2020'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:26:25

US3492117

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Clinic (Clinic)'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:26:25

US3492117

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'VISIT3'	System	06 Nov 2020 17:26:25

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '6 Nov 2020'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '11:10'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered '6 Nov 2020 11:10'	System	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '98.3' F	Gizelle Alvarez (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Other (Other)'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'tympanic'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '76'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'bpm'	System	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '16'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'breaths/min'	System	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '118'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'mmHg'	System	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '81'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'mmHg'	System	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41

US3492117

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:27:05

US3492117

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '6 Nov 2020'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:27:05

US3492117

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:27:14

US3492117

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '6 Nov 2020'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:27:14

US3492117

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered '11:20'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:27:14

US3492117

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered '6 Nov 2020 11:20'	System	06 Nov 2020 17:27:14

US3492117

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:17
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	06 Nov 2020 17:27:18

US3492117

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'I'	System	06 Nov 2020 17:27:18

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 64'	System	10 Sep 2020 19:59:02

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-11-10T08:01:57', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '86186806-b342-44ec-ac9a-5ad7677ca3eb' User entered 'No (N)'	System	10 Nov 2020 14:02:31
	System	10 Nov 2020 14:02:31

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-11-10T08:02:13', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '86186806-b342-44ec-ac9a-5ad7677ca3eb' User entered 'No (N)'	System	10 Nov 2020 14:02:31
	System	10 Nov 2020 14:02:31

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-11-10T08:02:26', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '86186806-b342-44ec-ac9a-5ad7677ca3eb' User entered '10 Nov 2020 08:02:26'	System	10 Nov 2020 14:02:31
	System	10 Nov 2020 14:02:31

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 19:59:02

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered 'Day 71'	System	10 Sep 2020 19:59:02

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-11-17T21:06:38', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'a413530e-5e82-469b-a9ba-d92761b7a780' User entered 'No (N)'	System	18 Nov 2020 03:07:12
	System	18 Nov 2020 03:07:12

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-11-17T21:07:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'a413530e-5e82-469b-a9ba-d92761b7a780'	System	18 Nov 2020 03:07:12
User entered 'No (N)'	System	18 Nov 2020 03:07:12

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-11-17T21:07:10', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'a413530e-5e82-469b-a9ba-d92761b7a780' User entered '17 Nov 2020 21:07:10'	System	18 Nov 2020 03:07:12
	System	18 Nov 2020 03:07:12

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 19:59:02

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:31:37
Data entry locked.	System	10 Sep 2020 19:59:02
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 19:59:02

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-11-22T11:45:02', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '21132dd2-2028-4a34-b4c9-501e9141fb2b'	System	22 Nov 2020 17:45:51
User entered 'No (N)'	System	22 Nov 2020 17:45:51

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-11-22T11:45:38', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '21132dd2-2028-4a34-b4c9-501e9141fb2b'	System	22 Nov 2020 17:45:51
User entered 'No (N)'	System	22 Nov 2020 17:45:51

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-11-22T11:45:46', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '21132dd2-2028-4a34-b4c9-501e9141fb2b'	System	22 Nov 2020 17:45:51
User entered '22 Nov 2020 11:45:46'	System	22 Nov 2020 17:45:51

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-11-30T01:17:37', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '7bf688ff-e26a-44b3-a60b-f08d70044a53'	System	30 Nov 2020 07:18:14
User entered 'No (N)'	System	30 Nov 2020 07:18:14

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-11-30T01:18:03', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '7bf688ff-e26a-44b3-a60b-f08d70044a53'	System	30 Nov 2020 07:18:14
User entered 'No (N)'	System	30 Nov 2020 07:18:14

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-11-30T01:18:11', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '7bf688ff-e26a-44b3-a60b-f08d70044a53' User entered '30 Nov 2020 01:18:11'	System	30 Nov 2020 07:18:14

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-12-06T07:30:23', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '81791700-e8a0-4c55-99f3-44222a112ac8' User entered 'No (N)'	System	06 Dec 2020 13:30:37
	System	06 Dec 2020 13:30:37

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-12-06T07:30:28', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '81791700-e8a0-4c55-99f3-44222a112ac8' User entered 'No (N)'	System	06 Dec 2020 13:30:37
	System	06 Dec 2020 13:30:37

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-12-06T07:30:34', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '81791700-e8a0-4c55-99f3-44222a112ac8' User entered '06 Dec 2020 07:30:34'	System	06 Dec 2020 13:30:37
	System	06 Dec 2020 13:30:37

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-12-14T05:06:35', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '3018645d-d385-405d-bd77-1bb959cf8188'	System	14 Dec 2020 11:06:44
User entered 'No (N)'	System	14 Dec 2020 11:06:44

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-12-14T05:04:45', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '3018645d-d385-405d-bd77-1bb959cf8188'	System	14 Dec 2020 11:06:44
User entered 'No (N)'	System	14 Dec 2020 11:06:44

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-12-14T05:06:41', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '3018645d-d385-405d-bd77-1bb959cf8188' User entered '14 Dec 2020 05:06:41'	System	14 Dec 2020 11:06:44
	System	14 Dec 2020 11:06:44

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-12-21T11:23:29', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '70e21134-5ae7-46d2-ac28-0cbef8b7e1cb' User entered 'No (N)'	System	21 Dec 2020 17:23:42
	System	21 Dec 2020 17:23:42

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-12-21T11:23:34', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '70e21134-5ae7-46d2-ac28-0cbef8b7e1cb' User entered 'No (N)'	System	21 Dec 2020 17:23:42

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-12-21T11:23:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '70e21134-5ae7-46d2-ac28-0cbef8b7e1cb' User entered '21 Dec 2020 11:23:39'	System	21 Dec 2020 17:23:42

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-12-26T05:24:18', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'ee6b03de-5d95-4e5d-8838-674be525f823' User entered 'Yes (Y)'	System	26 Dec 2020 11:25:34
	System	26 Dec 2020 11:25:34

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-12-26T05:24:23', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'ee6b03de-5d95-4e5d-8838-674be525f823' User entered 'No (N)'	System	26 Dec 2020 11:25:34
	System	26 Dec 2020 11:25:34

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-12-26T05:24:31', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'ee6b03de-5d95-4e5d-8838-674be525f823' User entered 'No (N)'	System	26 Dec 2020 11:25:34
	System	26 Dec 2020 11:25:34

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-12-26T05:25:03', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'ee6b03de-5d95-4e5d-8838-674be525f823'	System	26 Dec 2020 11:25:34
User entered 'No (N)'	System	26 Dec 2020 11:25:34

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2020-12-26T05:25:32', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'ee6b03de-5d95-4e5d-8838-674be525f823' User entered '26 Dec 2020 05:25:32'	System	26 Dec 2020 11:25:34
	System	26 Dec 2020 11:25:34

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-05T05:44:51', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9636fdc8-6a74-47ca-a950-af1b8dae5c85'	System	05 Jan 2021 11:45:07
User entered 'No (N)'	System	05 Jan 2021 11:45:07

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-05T05:44:57', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9636fdc8-6a74-47ca-a950-af1b8dae5c85'	System	05 Jan 2021 11:45:07
User entered 'No (N)'	System	05 Jan 2021 11:45:07

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-05T05:45:05', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9636fdc8-6a74-47ca-a950-af1b8dae5c85' User entered '05 Jan 2021 05:45:05'	System	05 Jan 2021 11:45:07
	System	05 Jan 2021 11:45:07

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-11T13:46:51', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'ac1a5e9e-989b-4e8e-b497-a9de060f2183' User entered 'No (N)'	System	11 Jan 2021 19:47:36
	System	11 Jan 2021 19:47:36

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-11T13:47:26', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'ac1a5e9e-989b-4e8e-b497-a9de060f2183' User entered 'No (N)'	System	11 Jan 2021 19:47:36

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-11T13:47:32', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'ac1a5e9e-989b-4e8e-b497-a9de060f2183' User entered '11 Jan 2021 13:47:32'	System	11 Jan 2021 19:47:36

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-16T09:10:14', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'b228fedb-f9df-44de-9cb7-09b1df85b18b'	System	16 Jan 2021 15:10:50
User entered 'No (N)'	System	16 Jan 2021 15:10:50

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-16T09:10:27', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'b228fedb-f9df-44de-9cb7-09b1df85b18b'	System	16 Jan 2021 15:10:50
User entered 'No (N)'	System	16 Jan 2021 15:10:50

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-16T09:10:46', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'b228fedb-f9df-44de-9cb7-09b1df85b18b' User entered '16 Jan 2021 09:10:46'	System	16 Jan 2021 15:10:50
	System	16 Jan 2021 15:10:50

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-27T13:31:34', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '92af4b53-c57d-4129-af07-5d30dbe4bebb' User entered 'No (N)'	System	27 Jan 2021 19:31:44

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-27T13:31:36', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '92af4b53-c57d-4129-af07-5d30dbe4bebb'	System	27 Jan 2021 19:31:44
User entered 'No (N)'	System	27 Jan 2021 19:31:44

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-27T13:31:41', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '92af4b53-c57d-4129-af07-5d30dbe4bebb' User entered '27 Jan 2021 13:31:41'	System	27 Jan 2021 19:31:44
	System	27 Jan 2021 19:31:44

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:31:01', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered 'Yes (Y)'	System	30 Jan 2021 11:34:12
	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:31:43', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered 'Yes (Y)'	System	30 Jan 2021 11:34:12
	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Please 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:31:49', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26'	System	30 Jan 2021 11:34:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:31:58', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered 'Yes (Y)'	System	30 Jan 2021 11:34:12
	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '1'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '0'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '0'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '0'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '0'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '0'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '1'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26'	System	30 Jan 2021 11:34:12
User entered '1'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '1'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '0'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '0'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '0'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '0'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '1'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '1'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '0'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:39', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '0'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Please 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:32:56', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26'	System	30 Jan 2021 11:34:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:33:08', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26'	System	30 Jan 2021 11:34:12
User entered 'Yes (Y)'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Please 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:33:31', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26'	System	30 Jan 2021 11:34:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-01-30T05:34:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '79d184c1-a40e-4510-89a3-7a28d4b2bf26' User entered '30 Jan 2021 05:34:00'	System	30 Jan 2021 11:34:12
	System	30 Jan 2021 11:34:12

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-06T08:41:22', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'c7652712-54cf-45f7-aac6-a8031ee261a7' User entered 'No (N)'	System	06 Feb 2021 14:41:45
	System	06 Feb 2021 14:41:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-06T08:41:36', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'c7652712-54cf-45f7-aac6-a8031ee261a7' User entered 'No (N)'	System	06 Feb 2021 14:41:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-06T08:41:41', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'c7652712-54cf-45f7-aac6-a8031ee261a7' User entered '06 Feb 2021 08:41:41'	System	06 Feb 2021 14:41:45
	System	06 Feb 2021 14:41:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-13T07:39:22', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '02839cbb-a56f-4d0e-a4ff-80ceb1fac125'	System	13 Feb 2021 13:39:37
User entered 'No (N)'	System	13 Feb 2021 13:39:37

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-13T07:39:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '02839cbb-a56f-4d0e-a4ff-80ceb1fac125'	System	13 Feb 2021 13:39:37
User entered 'No (N)'	System	13 Feb 2021 13:39:37

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-13T07:39:35', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '02839cbb-a56f-4d0e-a4ff-80ceb1fac125' User entered '13 Feb 2021 07:39:35'	System	13 Feb 2021 13:39:37
	System	13 Feb 2021 13:39:37

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-20T02:42:47', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '19be0340-f16f-4c23-9f15-5a93e308ba96'	System	20 Feb 2021 08:43:00
User entered 'No (N)'	System	20 Feb 2021 08:43:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-20T02:42:52', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '19be0340-f16f-4c23-9f15-5a93e308ba96'	System	20 Feb 2021 08:43:00
User entered 'No (N)'	System	20 Feb 2021 08:43:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-20T02:42:57', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '19be0340-f16f-4c23-9f15-5a93e308ba96' User entered '20 Feb 2021 02:42:57'	System	20 Feb 2021 08:43:00
	System	20 Feb 2021 08:43:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:29:33-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered 'Yes (Y)'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:29:59-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered 'No (N)'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:30:21-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered 'Yes (Y)'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '1'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '1'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '0'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '0'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '0'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '1'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '1'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '1'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '1'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '0'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '0'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '0'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '1'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '0'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '1'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '0'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:28-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '0'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Please 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:31:47-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:32:20-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered 'No (N)'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T03:32:36-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '9b20aed3-4061-4eb4-b4c0-fa89d531f106'	System	27 Feb 2021 09:32:45
User entered '27 Feb 2021 09:32:36'	System	27 Feb 2021 09:32:45

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-03-06T03:30:54-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f8484ed0-c1ee-4709-b774-cd0a3c923f26'	System	06 Mar 2021 09:31:11
User entered 'No (N)'	System	06 Mar 2021 09:31:11

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-03-06T03:31:03-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f8484ed0-c1ee-4709-b774-cd0a3c923f26'	System	06 Mar 2021 09:31:11
User entered 'No (N)'	System	06 Mar 2021 09:31:11

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-03-06T03:31:09-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'f8484ed0-c1ee-4709-b774-cd0a3c923f26'	System	06 Mar 2021 09:31:11
User entered '06 Mar 2021 03:31:09'	System	06 Mar 2021 09:31:11

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-03-14T00:26:29-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'c59e0aef-35cf-4368-ae93-9b96eef6e0d3'	System	14 Mar 2021 06:26:40
User entered 'No (N)'	System	14 Mar 2021 06:26:40

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-03-14T00:26:32-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'c59e0aef-35cf-4368-ae93-9b96eef6e0d3'	System	14 Mar 2021 06:26:40
User entered 'No (N)'	System	14 Mar 2021 06:26:40

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-03-14T00:26:37-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'c59e0aef-35cf-4368-ae93-9b96eef6e0d3' User entered '14 Mar 2021 00:26:37'	System	14 Mar 2021 06:26:40
	System	14 Mar 2021 06:26:40

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-03-20T05:41:44-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '82f91273-aceb-4fbf-b295-1e01985460f9'	System	20 Mar 2021 10:41:57
User entered 'No (N)'	System	20 Mar 2021 10:41:57

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-03-20T05:41:47-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '82f91273-aceb-4fbf-b295-1e01985460f9'	System	20 Mar 2021 10:41:57
User entered 'No (N)'	System	20 Mar 2021 10:41:57

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-03-20T05:41:52-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '82f91273-aceb-4fbf-b295-1e01985460f9' User entered '20 Mar 2021 05:41:52'	System	20 Mar 2021 10:41:57
	System	20 Mar 2021 10:41:57

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-03-27T04:01:51-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '8b795a6a-dfbc-4ddf-8d6c-aeaa633a1960'	System	27 Mar 2021 09:02:14
User entered 'No (N)'	System	27 Mar 2021 09:02:14

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-03-27T04:01:57-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '8b795a6a-dfbc-4ddf-8d6c-aeaa633a1960'	System	27 Mar 2021 09:02:14
User entered 'No (N)'	System	27 Mar 2021 09:02:14

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-03-27T04:02:03-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '8b795a6a-dfbc-4ddf-8d6c-aeaa633a1960'	System	27 Mar 2021 09:02:14
User entered '27 Mar 2021 04:02:03'	System	27 Mar 2021 09:02:14

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-04-03T05:01:06-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'd2af6269-8ab3-42df-b57a-7b08bf874f2c'	System	03 Apr 2021 10:01:18
User entered 'No (N)'	System	03 Apr 2021 10:01:18

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-04-03T05:01:09-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'd2af6269-8ab3-42df-b57a-7b08bf874f2c'	System	03 Apr 2021 10:01:18
User entered 'No (N)'	System	03 Apr 2021 10:01:18

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-04-03T05:01:13-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'd2af6269-8ab3-42df-b57a-7b08bf874f2c'	System	03 Apr 2021 10:01:18
User entered '03 Apr 2021 05:01:13'	System	03 Apr 2021 10:01:18

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-04-10T04:48:51-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '8e422a43-b95e-4f5e-804a-785035e1b8c5'	System	10 Apr 2021 09:49:01
User entered 'No (N)'	System	10 Apr 2021 09:49:01

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-04-10T04:48:53-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '8e422a43-b95e-4f5e-804a-785035e1b8c5'	System	10 Apr 2021 09:49:01
User entered 'No (N)'	System	10 Apr 2021 09:49:01

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-04-10T04:48:58-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '8e422a43-b95e-4f5e-804a-785035e1b8c5'	System	10 Apr 2021 09:49:01
User entered '10 Apr 2021 04:48:58'	System	10 Apr 2021 09:49:01

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-04-17T05:19:27-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '5e438c19-ac18-4386-a31b-cad82c352456'	System	17 Apr 2021 10:19:42
User entered 'No (N)'	System	17 Apr 2021 10:19:42

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-04-17T05:19:29-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '5e438c19-ac18-4386-a31b-cad82c352456'	System	17 Apr 2021 10:19:42
User entered 'No (N)'	System	17 Apr 2021 10:19:42

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-04-17T05:19:39-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '5e438c19-ac18-4386-a31b-cad82c352456' User entered '17 Apr 2021 05:19:39'	System	17 Apr 2021 10:19:42
	System	17 Apr 2021 10:19:42

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-04-24T02:38:37-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'd6443eb4-cae2-4bf2-85d1-c26ceb7990ef' User entered 'No (N)'	System	24 Apr 2021 07:39:18
	System	24 Apr 2021 07:39:18

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-04-24T02:39:02-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'd6443eb4-cae2-4bf2-85d1-c26ceb7990ef' User entered 'No (N)'	System	24 Apr 2021 07:39:18

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-04-24T02:39:14-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'd6443eb4-cae2-4bf2-85d1-c26ceb7990ef' User entered '24 Apr 2021 02:39:14'	System	24 Apr 2021 07:39:18
	System	24 Apr 2021 07:39:18

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-05-01T02:48:12-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'b9cca475-cf53-44ac-a30c-bb135d156682'	System	01 May 2021 07:48:35
User entered 'No (N)'	System	01 May 2021 07:48:35

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you been exposed to someone with 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 (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-05-01T02:48:19-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'b9cca475-cf53-44ac-a30c-bb135d156682'	System	01 May 2021 07:48:35
User entered 'No (N)'	System	01 May 2021 07:48:35

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-05-01T02:48:32-05:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'b9cca475-cf53-44ac-a30c-bb135d156682'	System	01 May 2021 07:48:35
User entered '01 May 2021 02:48:32'	System	01 May 2021 07:48:35

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:19:00

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:19:00

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 07:19:00

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:19:00

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:19:00

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 07:19:00

US3492117

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:51:43

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 13:15:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T14:57:42-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '00a38dac-cf5c-4338-93b9-b58737dcdd0c'	System	27 Feb 2021 20:58:16
User entered 'Yes (Y)'	System	27 Feb 2021 20:58:16

US3492117

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:51:43

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:15:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T14:57:59-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '00a38dac-cf5c-4338-93b9-b58737dcdd0c'	System	27 Feb 2021 20:58:16
User entered 'No (N)'	System	27 Feb 2021 20:58:16

US3492117

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:51:43

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:15:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5460062D-C420-4AA3-8859-1C2CD66B146B)', Time: '2021-02-27T14:58:05-06:00', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '00a38dac-cf5c-4338-93b9-b58737dcdd0c' User entered '27 Feb 2021 20:58:05'	System	27 Feb 2021 20:58:16
	System	27 Feb 2021 20:58:16

US3492117

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	02 Dec 2020 16:31:54

US3492117

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '1 Dec 2020'	Lorna Sanchez McCann (b) (4)	02 Dec 2020 16:31:54

US3492117

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Dec 2020 16:31:54

US3492117

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	(b) (4) Lorna Sanchez McCann	02 Dec 2020 16:31:54
	(b) (4)	

US3492117

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Dec 2020 16:32:00

US3492117

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:41
User entered 'I'	System	02 Dec 2020 16:32:00

US3492117

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Ian Feather (b) (4)	07 Jan 2021 14:42:41

US3492117

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '7 Jan 2021'	Ian Feather (b) (4)	07 Jan 2021 14:42:41

US3492117

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Contact Made (CONTACT MADE)'	Ian Feather (b) (4)	07 Jan 2021 14:42:41

US3492117

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Ian Feather (b) (4)	07 Jan 2021 14:42:41

US3492117

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Ian Feather (b) (4)	07 Jan 2021 14:42:45

US3492117

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User entered 'I'	System	07 Jan 2021 14:42:45

US3492117

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Ian Feather (b) (4)	02 Feb 2021 17:04:30

US3492117

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '2 Feb 2021'	Ian Feather (b) (4)	02 Feb 2021 17:04:30

US3492117

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Contact Made (CONTACT MADE)'	Ian Feather (b) (4)	02 Feb 2021 17:04:30

US3492117

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Ian Feather (b) (4)	02 Feb 2021 17:04:30

US3492117

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Ian Feather (b) (4)	02 Feb 2021 17:04:34

US3492117

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User entered 'I'	System	02 Feb 2021 17:04:34

US3492117

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:30:43

US3492117

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:30:43

US3492117

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:30:43

US3492117

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:30:43

US3492117

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:31:02

US3492117

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:32:06
User entered 'I'	System	04 Mar 2021 15:31:02

US3492117

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:49:24

US3492117

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '26 Mar 2021'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:49:24
	(b) (4)	

US3492117

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[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 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered 'Clinic (Clinic)'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:49:24
	(b) (4)	

US3492117

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User entered 'VISIT4'	System	26 Mar 2021 16:49:24

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered 'Yes (Y)'	Marla Schwarber (b) (4)	30 Mar 2021 21:54:36

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '26 Mar 2021'	(b) (4) Marla Schwarber (b) (4)	30 Mar 2021 21:54:36

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '11:35'	Marla Schwarber (b) (4)	30 Mar 2021 21:54:36

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User entered '26 Mar 2021 11:35'	System	30 Mar 2021 21:54:36

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '98.6' F	Marla Schwarber (b) (4)	30 Mar 2021 21:54:36

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered 'Other (Other)'	Marla Schwarber (b) (4)	30 Mar 2021 21:54:36

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered 'tympanic'	Marla Schwarber (b) (4)	30 Mar 2021 21:54:36

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '69'	Marla Schwarber (b) (4)	30 Mar 2021 21:54:36

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User entered 'bpm'	System	30 Mar 2021 21:54:36

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '18'	Marla Schwarber (b) (4)	30 Mar 2021 21:54:36

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User entered 'breaths/min'	System	30 Mar 2021 21:54:36

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '143'	Marla Schwarber (b) (4)	30 Mar 2021 21:54:36

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User entered 'mmHg'	System	30 Mar 2021 21:54:36

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '76'	Marla Schwarber (b) (4)	30 Mar 2021 21:54:36

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User entered 'mmHg'	System	30 Mar 2021 21:54:36

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52

US3492117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52

US3492117

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:49:34

US3492117

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '26 Mar 2021'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:49:34

US3492117

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:49:51

US3492117

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '26 Mar 2021'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:49:51

US3492117

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '11:35'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:49:51

US3492117

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User entered '26 Mar 2021 11:35'	System	26 Mar 2021 16:49:51

US3492117

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:49:56

US3492117

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:52
User entered 'I'	System	26 Mar 2021 16:49:56

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Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 16:55:56

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Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
User entered '03 May 2021'	(b) (4), (b) (6)	03 May 2021 16:55:56

US3492117

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 May 2021 16:55:56

US3492117

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 16:55:56

US3492117

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 16:56:07

US3492117

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 16:56:07

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:51:43

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:35:55
User entered '22 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:03:04
User entered '23 Sep 2020'	(b) (4) Andrea Wendrow (b) (4)	23 Sep 2020 21:27:10

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:51:43

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:35:55
User entered '10:00'	Andrea Wendrow (b) (4) (b) (4)	23 Sep 2020 21:27:10

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:51:43

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:23
User entered '22 Sep 2020 10:00'	System	03 Oct 2020 20:03:04
User entered '23 Sep 2020 10:00'	System	23 Sep 2020 21:27:10

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:51:43

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:35:55
User closed query 'Per CDM: Please reconcile type of visit as there are Safety Calls with this date and update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:51:36
Query 'Per CDM: Please reconcile type of visit as there are Safety Calls with this date and update accordingly.' answered with 'this is correct' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:18:39
User opened query 'Per CDM: Please reconcile type of visit as there are Safety Calls with this date and update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 01:23:52
User entered 'Safety Call (Safety Call)'	Andrea Wendrow (b) (4) (b) (4)	23 Sep 2020 21:27:10

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:51:43

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:35:55
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	23 Sep 2020 21:27:10

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	(b) (4) Andrea Wendrow (b) (4)	03 Oct 2020 20:00:41
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	(b) (4) Andrea Wendrow (b) (4)	03 Oct 2020 19:59:26
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 19:30:54
User entered 'Day 2 (Day 2)'	(b) (4) Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User closed query 'Per CDM: previous response is noted; however it appears initial start date of symptoms and Contact Date are the same (22SEP2020). Please confirm or update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:03:37
Query 'Per CDM: previous response is noted; however it appears initial start date of symptoms and Contact Date are the same (22SEP2020). Please confirm or update accordingly.' answered with 'confirmed' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	11 Nov 2020 03:41:34
User opened query 'Per CDM: previous response is noted; however it appears initial start date of symptoms and Contact Date are the same (22SEP2020). Please confirm or update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:41:51
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User closed query 'Per ETRTR: Please consider adding Symptoms previous to Illness Visit, per AE Narrative some were reported on 22Sep20, thanks.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:18:31
User entered '22 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:00:14
User entered '23 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 19:59:26
Query 'Per ETRTR: Please consider adding Symptoms previous to Illness Visit, per AE Narrative some were reported on 22Sep20, thanks.' answered with 'corrected' (Site from CRA).	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 19:53:51
User entered '22 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 19:53:40
User opened query 'Per ETRTR: Please consider adding Symptoms previous to Illness Visit, per AE Narrative some were reported on 22Sep20, thanks.' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 21:11:51
User entered '23 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	23 Sep 2020 21:29:18

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '1' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:00:41
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered '99'	(b) (4) Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User entered empty.	System	03 Oct 2020 20:02:20
User entered '%'	System	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered '100.7' F	(b) (4) Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	23 Sep 2020 21:30:31
User entered empty.	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Andrea Wendrow (b) (4)	23 Sep 2020 21:30:31
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	23 Sep 2020 21:30:31
User entered empty.	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	23 Sep 2020 21:30:31
User entered empty.	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered 'Severe (Severe)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	23 Sep 2020 21:30:31
User entered empty.	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered 'Severe (Severe)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	23 Sep 2020 21:30:31
User entered empty.	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered 'Severe (Severe)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	23 Sep 2020 21:30:31
User entered empty.	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	23 Sep 2020 21:30:31
User entered empty.	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	23 Sep 2020 21:30:31
User entered empty.	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	23 Sep 2020 21:30:31
User entered empty.	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	23 Sep 2020 21:30:31
User entered empty.	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	23 Sep 2020 21:30:31
User entered empty.	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	23 Sep 2020 21:30:31
User entered empty.	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	23 Sep 2020 21:30:31
User entered empty.	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:02:20
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	23 Sep 2020 21:30:31
User entered empty.	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Day 2 (Day 2)'	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '23 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:00:04
User entered '24 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:58:38
User entered '23 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:54:08
User entered '24 Sep 2020'	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Oct 2020 15:22:38
User entered '1'	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '98' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User entered '%'	System	03 Oct 2020 20:10:25
User entered empty.	System	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '100.7' F reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Severe (Severe)' reason for change:	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
Data Entry Error	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Severe (Severe)' reason for change:	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
Data Entry Error	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Severe (Severe)' reason for change:	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
Data Entry Error	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:10:25
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Day 4 (Day 4)' reason for change:	(b) (4)	
Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:16
User entered 'Day 3 (Day 3)'	(b) (4)	
	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '25 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:58:27
User entered '24 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:54:23
User entered '25 Sep 2020'	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'I'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User entered empty.	System	26 Sep 2020 20:57:58

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 20:57:58

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Day 5 (Day 5)' reason for change:	(b) (4)	
Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:16
User entered 'Day 4 (Day 4)'	(b) (4)	
	Richard Novak (b) (4)	27 Sep 2020 19:04:23
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '26 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:58:15
User entered '25 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:54:34
User entered '26 Sep 2020'	Richard Novak (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '96'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User entered '%'	System	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '98.3' F	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Moderate (Moderate)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Moderate (Moderate)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:04:23

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Day 6 (Day 6)' reason for change:	(b) (4)	
Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:16
User entered 'Day 5 (Day 5)'	(b) (4)	
	Richard Novak (b) (4)	27 Sep 2020 19:07:05
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '27 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:58:06
User entered '26 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:54:46
User entered '27 Sep 2020'	Richard Novak (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '96'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User entered '%'	System	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '98.1' F	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Moderate (Moderate)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Moderate (Moderate)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:07:05

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Day 7 (Day 7)' reason for change: New Information	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:16
User entered 'Day 6 (Day 6)' reason for change: New Information	Richard Novak (b) (4)	30 Sep 2020 20:46:25
User entered empty.	Richard Novak (b) (4)	27 Sep 2020 19:10:09

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '28 Sep 2020' reason for change: New Information	Andrea Wendrow (b) (4)	03 Oct 2020 19:57:56
User entered '27 Sep 2020' reason for change: New Information	Andrea Wendrow (b) (4)	03 Oct 2020 19:55:00
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 21:09:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 21:09:42
User entered '28 Sep 2020' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Sep 2020 19:10:09
User entered empty.	Richard Novak (b) (4)	27 Sep 2020 19:10:09

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '97' reason for change: New Information	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User entered '%'	System	28 Sep 2020 21:09:42
User entered empty.	System	27 Sep 2020 19:10:09

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '101.2' F reason for change: New Information	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25
User entered '98.1' F reason for change: Data Entry Error	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Moderate (Moderate)' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Moderate (Moderate)' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4) (b) (4)	27 Sep 2020 19:10:09

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Day 8 (Day 8)' reason for change:	(b) (4)	
Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:16
User entered 'Day 7 (Day 7)'	(b) (4)	
	Richard Novak (b) (4)	30 Sep 2020 20:46:25
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '29 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:57:41
User entered '28 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:55:15
User entered '29 Sep 2020'	Richard Novak (b) (4)	30 Sep 2020 20:46:25

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '98'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User entered '%'	System	30 Sep 2020 20:46:25

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '98.2' F	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:48:27
User entered empty.	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:48:27
User entered empty.	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:48:27
User entered empty.	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:48:27
User entered empty.	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:48:27
User entered empty.	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:48:27
User entered empty.	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: New Information	Richard Novak (b) (4)	30 Sep 2020 20:48:27
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:48:27
User entered empty.	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:48:27
User entered empty.	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: New Information	Richard Novak (b) (4)	30 Sep 2020 20:48:27
User entered empty.	(b) (4) Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:48:27
User entered empty.	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:48:27
User entered empty.	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:48:27
User entered empty.	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Day 9 (Day 9)' reason for change:	(b) (4)	
Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:16
User entered 'Day 8 (Day 8)'	(b) (4)	
	Richard Novak (b) (4)	30 Sep 2020 20:51:03
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '30 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:57:30
User entered '29 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:55:31
User entered '30 Sep 2020'	Richard Novak (b) (4)	30 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '96'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User entered '%'	System	30 Sep 2020 20:51:03

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '99.7' F	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Day 10 (Day 10)' reason for change:	(b) (4)	
Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:16
User entered 'Day 9 (Day 9)'	(b) (4)	
	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '01 Oct 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:57:20
User entered '30 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:55:50
User entered '1 Oct 2020'	Richard Novak (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '96'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User entered '%'	System	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '99.2' F	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Moderate (Moderate)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:51:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:13:16

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:16
User entered 'Day 10 (Day 10)'	(b) (4)	
	Richard Novak (b) (4)	02 Oct 2020 21:15:17
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '02 Oct 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:57:04
User entered '1 Oct 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:56:37
User entered '2 Oct 2020'	Richard Novak (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '96'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User entered '%'	System	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '100.0' F	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:51:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:15:17

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Day 3 (Day 3)'	(b) (4) Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '24 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'l'	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User entered empty.	System	03 Oct 2020 20:12:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:51:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:56

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Day 12 (Day 12)'	Richard Novak (b) (4)	04 Oct 2020 20:44:30

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '3 Oct 2020'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '95'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User entered '%'	System	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '102.2' F	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Moderate (Moderate)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:51:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:44:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Day 13 (Day 13)'	Richard Novak (b) (4)	04 Oct 2020 20:46:46

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '4 Oct 2020'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '96'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User entered '%'	System	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '102.0' F	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:51:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Day 14 (Day 14)'	(b) (4) Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User closed query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 20OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 11:37:55
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 20OCT2020. Please reconcile or clarify.' answered with 'no this is correct' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	11 Nov 2020 03:44:23
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 20OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:42:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '5 Oct 2020'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '95'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User entered '%'	System	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '101.0' F	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:51:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:35
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:51:43

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:15
Query 'Per GCL Lab Recon: GCL has Saliva Day 3, Day 5, Day 7, and Day 9 with dates of 25SEP2020, 28SEP2020, 29SEP2020, and 01OCT2020, respectively; however there is no Saliva Log completed. Please reconcile or clarify ' canceled (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:14:43
User opened query 'Per GCL Lab Recon: GCL has Saliva Day 3, Day 5, Day 7, and Day 9 with dates of 25SEP2020, 28SEP2020, 29SEP2020, and 01OCT2020, respectively; however there is no Saliva Log completed. Please reconcile or clarify ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:14:22
Query 'Per CDM: it appears there is an Illness Visit, which should have been an Unscheduled Visit, with this same date. Illness Visits are required after positive results are received. Please reconcile and update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:53:38
User opened query 'Per CDM: it appears there is an Illness Visit, which should have been an Unscheduled Visit, with this same date. Illness Visits are required after positive results are received. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 01:25:49
User entered '23 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:30:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:51:43

[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 03:16:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:15
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:30:56

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:51:43

[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 03:16:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:15
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)	01 Oct 2020 10:12:08
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 'done' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	28 Sep 2020 22:22:31
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	26 Sep 2020 18:30:56
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:30:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:51:43

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:45
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Response to previous query is noted that the sample dated 24-Sep-2020 was for the Biofire respiratory panel. However, per PPD Central Lab there is a Swab Sample dated 24-Sep-2020 (Accession No: 1F651111660 and Requisition Kit ID: 1F616973906) and this is missing in EDC. Kindly consider initiating Covid -19 Assessment eCRF for the corresponding date (24-Sep-2020) and updating Swab data in the COVID Diagnostic form so that data can be reconciled. Else, clarify. Thank you.	(b) (4), (b) (6)	29 Apr 2021 04:32:39
' (Site from DM). Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Response to previous query is noted that the sample dated 24-Sep-2020 was for the Biofire respiratory panel. However, per PPD Central Lab there is a Swab Sample dated 24-Sep-2020 (Accession No: 1F651111660 and Requisition Kit ID: 1F616973906) and this is missing in EDC. Kindly consider initiating Covid -19 Assessment eCRF for the corresponding date (24-Sep-2020) and updating Swab data in the COVID Diagnostic form so that data can be reconciled. Else, clarify. Thank you.	Andrea Wendrow (b) (4)	(b) (4) 10 Apr 2021 19:16:03
' answered with 'This is the COVID Diagnostic Test form for the COVID-19 assessment folder. The date of 22Sep2020 was the date of initial contact. 23Sep2020 was the date of the illness visit and that is the date the COVID PCR SWAB, which is this form, was collected. As this was the very first illness we ever did, the Biofire was missed and we collected it on the second day of the illness period. Does this help clarify?' (Site from DM).		

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Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:51:43

[Date of Test](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Response to previous query is noted that the sample dated 24-Sep-2020 was for the Biofire respiratory panel. However, per PPD Central Lab there is a Swab Sample dated 24-Sep-2020 (Accession No: 1F651111660 and Requisition Kit ID: 1F616973906) and this is missing in EDC. Kindly consider initiating Covid -19 Assessment eCRF for the corresponding date (24-Sep-2020) and updating Swab data in the COVID Diagnostic form so that data can be reconciled. Else, clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 08:16:05
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Response to previous query is noted that the sample dated 24-Sep-2020 was for the Biofire respiratory panel. However, per PPD Central Lab there is a Swab Sample dated 23-Sep-2020 (Accession No: 1F638004268 and Requisition Kit ID: 1F619039954) and this is missing in EDC. Kindly consider initiating Covid -19 Assessment eCRF for the corresponding date (23-Sep-2020) and updating Swab data in the COVID Diagnostic form so that data can be reconciled. Else, clarify. Thank you.	(b) (4), (b) (6)	22 Mar 2021 08:13:54
' canceled (Site from DM). User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Response to previous query is noted that the sample dated 24-Sep-2020 was for the Biofire respiratory panel. However, per PPD Central Lab there is a Swab Sample dated 23-Sep-2020 (Accession No: 1F638004268 and Requisition Kit ID: 1F619039954) and this is missing in EDC. Kindly consider initiating Covid -19 Assessment eCRF for the corresponding date (23-Sep-2020) and updating Swab data in the COVID Diagnostic form so that data can be reconciled. Else, clarify. Thank you.	(b) (4), (b) (6)	22 Mar 2021 08:12:39
' (Site from DM). User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:47:02

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:51:43

[Date of Test](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 23SEP2020 is recorded under Covid-19 Assessments visit in EDC, however the same is reported under Illness Visit Day 1 visit in GCL. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:41:45
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 23SEP2020 is recorded under Covid-19 Assessments visit in EDC, however the same is reported under Illness Visit Day 1 visit in GCL. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'this is correct' (Site from DM).	Andrea Wendrow (b) (4)	11 Nov 2020 03:38:54
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 23SEP2020 is recorded under Covid-19 Assessments visit in EDC, however the same is reported under Illness Visit Day 1 visit in GCL. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 04:46:10
User closed query 'per GCL Lab Recon: GCL has swab sample dated 24SEP2020, data for that date not present in CRF, please clarify or reconcile' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:31:10
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:15
Query 'per GCL Lab Recon: GCL has swab sample dated 24SEP2020, data for that date not present in CRF, please clarify or reconcile' answered with 'that swab sample on 24Sep2020 was for the BioFire respiratory panel' (Site from DM).	Andrea Wendrow (b) (4)	01 Nov 2020 21:20:12
User opened query 'per GCL Lab Recon: GCL has swab sample dated 24SEP2020, data for that date not present in CRF, please clarify or reconcile' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:13:20
User entered '23 Sep 2020'	Andrea Wendrow (b) (4)	26 Sep 2020 18:30:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:51:43

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:15
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:30:56

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:51:43

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:15
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:30:56

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[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 03:16:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:15
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:30:56

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:15
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:30:56

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:45
User entered 'I'	System	26 Sep 2020 18:30:56

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Form: Covid-19 Severity Assessment

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Did the subject have Respiratory Rates ≥ 30 per Minute?

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 19:22:30

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[Start Date](#)

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[End Date](#)

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[Respiratory Rate](#)

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
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Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
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[Heart Rate](#)

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Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
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[Start Date](#)

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[Oxygen Saturation](#)

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
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[PaO2](#)

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[Did the subject have Respiratory failure?](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
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[High-Flow Oxygen?](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
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[Non-Invasive Ventilation?](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
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[Mechanical Ventilation?](#)

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[ECMO?](#)

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

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[Evidence of Shock Requires
Vasopressors](#)

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[Acute Renal Dysfunction?](#)

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:51:43

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:51:43

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:51:43

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:51:43

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:51:43

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:51:43

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:51:43

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:51:43

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:51:43

[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 03:16:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:51:43

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:51:43

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:16:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:51:43

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:17:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per PPD portal, swab sample was collected on 24-SEP-2020 at illness visit & per response, "No, that is for the biofire respiratory swab barcode 1F651111660"; however, swab sample for 24 SEP 2020 is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for 24-SEP-2020 and updating swab data in the COVID Diagnostic form, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 05:42:11
Query 'Per GCL Lab Reconciliation requery: Swab: Per PPD portal, swab sample was collected on 24-SEP-2020 at illness visit & per response, "No, that is for the biofire respiratory swab barcode 1F651111660"; however, swab sample for 24 SEP 2020 is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for 24-SEP-2020 and updating swab data in the COVID Diagnostic form, else clarify.' answered with 'It was collected on DAY2 of illness visit that started 23Sep2020. The COVID-19 Assessment 24Sep was initiated in error, it is not another illness visit. We collected the Biofire on Day 2 instead of Day 1 as we did not have the VTM on Day 1' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	31 Dec 2020 18:33:09
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per PPD portal, swab sample was collected on 24-SEP-2020 at illness visit & per response, "No, that is for the biofire respiratory swab barcode 1F651111660"; however, swab sample for 24 SEP 2020 is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for 24-SEP-2020 and updating swab data in the COVID Diagnostic form, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 12:05:03

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:51:43

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Illness Visit Day 1 COVID PCR Swab sample collected on 24SEP2020, however, this sample is not recorded in EDC. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 12:05:03
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Illness Visit Day 1 COVID PCR Swab sample collected on 24SEP2020, however, this sample is not recorded in EDC. Please clarify and update as appropriate.' answered with 'No, that is for the biofire respiratory swab barcode 1F651111660' (Site from DM).	Andrea Wendrow (b) (4)	14 Dec 2020 19:51:11
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Illness Visit Day 1 COVID PCR Swab sample collected on 24SEP2020, however, this sample is not recorded in EDC. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 20:16:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:29
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	26 Sep 2020 19:32:17
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	23 Sep 2020 21:30:44

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:51:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:51:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:51:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25SEP2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 06:59:29
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25SEP2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'it is 1F619514988. The date in PPD is incorrect. It should be 25Sep2020' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	04 Dec 2020 19:36:48
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25SEP2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 07:54:52
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered '25 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:51:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:51:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:51:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:43
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27SEP2020 is recorded under Illness Visit Day 5 visit in EDC, however the same is reported with date 28SEP2020 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)	03 Nov 2020 23:13:52
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27SEP2020 is recorded under Illness Visit Day 5 visit in EDC, however the same is reported with date 28SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'correct date is 27Sep2020' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:17:43
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27SEP2020 is recorded under Illness Visit Day 5 visit in EDC, however the same is reported with date 28SEP2020 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 05:38:42
User entered '27 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:51:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Andrea Wendrow (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:51:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:51:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User closed query 'Per GCL Reconciliation: Saliva sample collected on 29SEP2020 is labelled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 04:50:09
Query 'Per GCL Reconciliation: Saliva sample collected on 29SEP2020 is labelled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date.' answered with 'correct is illness Day 7' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	11 Nov 2020 03:39:55
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:43
User opened query 'Per GCL Reconciliation: Saliva sample collected on 29SEP2020 is labelled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:45:54
User entered '29 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:51:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:51:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:51:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered '1 Oct 2020'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:51:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:51:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:21:45
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:51:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered '06 Oct 2020' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:21:45
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:51:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Andrea Wendrow (b) (4)	19 Oct 2020 22:04:33
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:51:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:21:45
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:51:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered '13 Oct 2020' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:21:45
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:51:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:51:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:43
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:21:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 21:21:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:21:45
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 22:04:33
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:51:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered '20 Oct 2020' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:21:45
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:47
Query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 04:48:18
User opened query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 21:12:23
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:52:10

US3492117

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:47
User entered '23 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:52:10

US3492117

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[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 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:47
User entered 'Home (Home)'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:52:10

US3492117

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User entered 'SICKD1'	System	26 Sep 2020 18:52:10

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered '23 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered '12:20'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User entered '23 Sep 2020 12:20'	System	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered missing code ND - Not Done.	Andrea Wendrow (b) (4)	26 Sep 2020 18:57:52
DataPoint set to visible.	(b) (4) System	26 Sep 2020 18:52:10

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered missing code ND - Not Done.	Andrea Wendrow (b) (4)	26 Sep 2020 18:57:52
DataPoint set to visible.	(b) (4) System	26 Sep 2020 18:52:10

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered '100.7' F	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered 'Oral (Oral)'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered '82'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User entered 'bpm'	System	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered '14'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User entered 'breaths/min'	System	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered '144'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User entered 'mmHg'	System	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered '91'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User entered 'mmHg'	System	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17

US3492117

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:01
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:58:11

US3492117

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:01
User entered '23 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 18:58:11

US3492117

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:51:43

[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 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:05
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 19:10:45

US3492117

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:51:43

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:05
User entered '23 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 19:10:45

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:10
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:10:53

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:10
User entered '20 Oct 2020'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:10:53

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:10
User entered 'Clinic (Clinic)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:10:53

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User entered 'SICKD28'	System	20 Oct 2020 21:10:53

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered '20 Oct 2020'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered '15:50'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User entered '20 Oct 2020 15:50'	System	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered missing code ND - Not Done.	Diana Bahena (b) (4)	20 Oct 2020 21:12:09
DataPoint set to visible.	(b) (4) System	20 Oct 2020 21:10:53

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered missing code ND - Not Done.	Diana Bahena (b) (4)	20 Oct 2020 21:12:09
DataPoint set to visible.	(b) (4) System	20 Oct 2020 21:10:53

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered '99' F	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered 'Other (Other)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered 'tympanic'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered '73'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User entered 'bpm'	System	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered '16'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User entered 'breaths/min'	System	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered '142'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User entered 'mmHg'	System	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered '80'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User entered 'mmHg'	System	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:24
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:12:19

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:24
User entered '20 Oct 2020'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:12:19

US3492117

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:51:43

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:28
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:12:33

US3492117

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:51:43

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:42:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:37:28
User entered '20 Oct 2020'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:12:33

US3492117

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

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:40:02

US3492117

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

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '29 Jan 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:40:02

US3492117

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

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Clinic (Clinic)'	Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:40:02

US3492117

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

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'UNBLND_DECIDE'	System	29 Jan 2021 17:40:02

US3492117

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '29 Jan 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:40:20

US3492117

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[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 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:07:21

US3492117

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:40:20

US3492117

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:07:21

US3492117

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '29 Jan 2021'	Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:40:20

US3492117

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Placebo (Placebo)'	Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:40:20

US3492117

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Placebo (Placebo)'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:40:20

US3492117

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Not Administered (NA)'	Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:40:20

US3492117

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:40:20

US3492117

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered '1'	System	29 Jan 2021 17:40:20

US3492117

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'I'	System	29 Jan 2021 17:40:20

US3492117

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

US3492117

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

US3492117

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered empty.	System	29 Jan 2021 17:42:06
DataPoint set to visible.	System	29 Jan 2021 17:40:20

US3492117

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

US3492117

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

US3492117

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered empty.	System	29 Jan 2021 17:42:06
DataPoint set to visible.	System	29 Jan 2021 17:40:20

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User accepted default value 'Pre-Dose (PREDOSE)'	Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

US3492117

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '29 Jan 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '11:35'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

US3492117

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered '29 Jan 2021 11:35'	System	29 Jan 2021 17:42:06

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '98.4' F	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

US3492117

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Other (Other)'	Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'tympanic'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '68'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

US3492117

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'bpm'	System	29 Jan 2021 17:42:06

US3492117

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '18'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

US3492117

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'breaths/min'	System	29 Jan 2021 17:42:06

US3492117

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '143'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'mmHg'	System	29 Jan 2021 17:42:06

US3492117

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '88'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'mmHg'	System	29 Jan 2021 17:42:06

US3492117

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

US3492117

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:06

US3492117

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered empty.	System	29 Jan 2021 17:42:06
DataPoint set to visible.	System	29 Jan 2021 17:40:20

US3492117

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User accepted default value 'Post-Dose (POSTDOSE)'	Marla Schwarber (b) (4) (b) (4)	29 Jan 2021 18:49:10

US3492117

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Marla Schwarber (b) (4)	29 Jan 2021 18:49:10

US3492117

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '29 Jan 2021'	Marla Schwarber (b) (4)	29 Jan 2021 18:49:10

US3492117

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '12:30'	Marla Schwarber (b) (4)	29 Jan 2021 18:49:10

US3492117

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered '29 Jan 2021 12:30'	System	29 Jan 2021 18:49:10

US3492117

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '36.9' C	Marla Schwarber (b) (4)	29 Jan 2021 18:49:10

US3492117

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Other (Other)'	Marla Schwarber (b) (4)	29 Jan 2021 18:49:10

US3492117

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Tympanic'	Marla Schwarber (b) (4)	29 Jan 2021 18:49:10

US3492117

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '69'	Marla Schwarber (b) (4)	29 Jan 2021 18:49:10

US3492117

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'bpm'	System	29 Jan 2021 18:49:10

US3492117

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '14'	Marla Schwarber (b) (4)	29 Jan 2021 18:49:10

US3492117

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'breaths/min'	System	29 Jan 2021 18:49:10

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '160'	Marla Schwarber (b) (4)	29 Jan 2021 18:49:10

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'mmHg'	System	29 Jan 2021 18:49:10

US3492117

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '91'	Marla Schwarber (b) (4)	29 Jan 2021 18:49:10

US3492117

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'mmHg'	System	29 Jan 2021 18:49:10

US3492117

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:13

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:46:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '29 Jan 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:13

US3492117

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	(b) (4) Marla Schwarber (b) (4) (b) (4)	29 Jan 2021 18:21:15

US3492117

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Marla Schwarber (b) (4)	29 Jan 2021 18:21:15

US3492117

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

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 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Marla Schwarber (b) (4)	29 Jan 2021 18:21:15

US3492117

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'mRNA-1273'	System	29 Jan 2021 18:21:15
DataPoint set to visible.	System	29 Jan 2021 17:40:20

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '29 Jan 2021'	(b) (4) Marla Schwarber (b) (4) (b) (4)	29 Jan 2021 18:21:15

US3492117

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '12:15'	(b) (4) Marla Schwarber (b) (4) (b) (4)	29 Jan 2021 18:21:15

US3492117

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered '29 Jan 2021 12:15'	System	29 Jan 2021 18:21:15

US3492117

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Left Arm (LEFT ARM)'	Marla Schwarber (b) (4)	29 Jan 2021 18:21:15

US3492117

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:00
User entered 'ONCE'	System	29 Jan 2021 18:21:15

US3492117

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'INTRAMUSCULAR'	System	29 Jan 2021 18:21:15

US3492117

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:26

US3492117

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '29 Jan 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:26

US3492117

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '11:28'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:26

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered '29 Jan 2021 11:28'	System	29 Jan 2021 17:42:26

US3492117

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:40
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:35

US3492117

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:51:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:40
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 24SEP2020 is recorded under Illness Visit Day 1 in PPD Central lab, however the same collection date is recorded in Covid-19 Assessments and corresponding visit details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 04:33:46
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 24SEP2020 is recorded under Illness Visit Day 1 in PPD Central lab, however the same collection date is recorded in Covid-19 Assessments and corresponding visit details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' answered with 'This has been answered in another query under the Assessment folder, not sure why it is in here' (Site from DM).	Andrea Wendrow (b) (4)	10 Apr 2021 19:17:30
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 24SEP2020 is recorded under Illness Visit Day 1 in PPD Central lab, however the same collection date is recorded in Covid-19 Assessments and corresponding visit details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 08:27:16
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '29 Jan 2021'	Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:35

US3492117

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:51:43

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:40
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '11:31'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:35

US3492117

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:51:43

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:40
User entered '29 Jan 2021 11:31'	System	29 Jan 2021 17:42:35

US3492117

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

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	29 Jan 2021 17:42:39

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

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'I'	System	29 Jan 2021 17:42:39

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	05 Feb 2021 16:16:53

US3492117

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '5 Feb 2021'	(b) (4) Nia Moragne-O'Neal (b) (4)	05 Feb 2021 16:16:53

US3492117

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	05 Feb 2021 16:16:53

US3492117

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:47:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Nia Moragne-O'Neal (b) (4)	05 Feb 2021 16:16:53

US3492117

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	05 Feb 2021 16:16:59

US3492117

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'I'	System	05 Feb 2021 16:16:59

US3492117

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'I'	System	05 Feb 2021 16:16:59
DataPoint set to visible.	System	05 Feb 2021 16:16:59

US3492117

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:47:52
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:53:10

US3492117

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:47:52
User entered '25 Feb 2021' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	27 Feb 2021 18:47:22
User entered '26 Feb 2021'	Gizelle Alvarez (b) (4)	26 Feb 2021 16:53:10

US3492117

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:47:52
User entered 'Clinic (Clinic)'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:53:10

US3492117

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'OLD29'	System	26 Feb 2021 16:53:10

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User accepted default value 'Pre-Dose (PREDOSE)'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	27 Feb 2021 18:47:38
User entered '25 Feb 2021' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	27 Feb 2021 18:47:38
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	27 Feb 2021 18:47:22
User entered '26 Feb 2021'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered '11:09'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered '25 Feb 2021 11:09'	System	27 Feb 2021 18:47:38
User entered '26 Feb 2021 11:09'	System	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered '97.6' F	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered 'Other (Other)'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered 'tympanic'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered '72'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'bpm'	System	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered '18'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'breaths/min'	System	26 Feb 2021 16:54:48

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered '144'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'mmHg'	System	26 Feb 2021 16:54:48

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered '67'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'mmHg'	System	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User accepted default value 'Post-Dose (POSTDOSE)'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	27 Feb 2021 18:47:38
User entered '25 Feb 2021' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	27 Feb 2021 18:47:38
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	27 Feb 2021 18:47:22
User entered '26 Feb 2021'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered '12:15'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered '25 Feb 2021 12:15'	System	27 Feb 2021 18:47:38
User entered '26 Feb 2021 12:15'	System	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered '36.5' C	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered 'Other (Other)'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered 'tympanic'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered '62'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'bpm'	System	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered '16'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'breaths/min'	System	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered '146'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'mmHg'	System	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:13
User entered '90'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'mmHg'	System	26 Feb 2021 16:54:48

US3492117

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:25
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:53:18

US3492117

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:25
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	27 Feb 2021 18:52:11
User entered '25 Feb 2021' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	27 Feb 2021 18:52:11
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	27 Feb 2021 18:47:22
User entered '26 Feb 2021'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:53:18

US3492117

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:31
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:55:04

US3492117

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:31
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:55:04

US3492117

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

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 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:31
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:55:04

US3492117

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'mRNA-1273'	System	26 Feb 2021 16:55:04
DataPoint set to visible.	System	05 Feb 2021 16:16:59

US3492117

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:31
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	27 Feb 2021 18:52:44
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	27 Feb 2021 18:52:44
User entered '25 Feb 2021' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	27 Feb 2021 18:52:44
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	27 Feb 2021 18:47:22
User entered '26 Feb 2021'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:55:04

US3492117

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:31
User entered '12:12'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:55:04

US3492117

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered '25 Feb 2021 12:12'	System	27 Feb 2021 18:52:44
User entered '26 Feb 2021 12:12'	System	26 Feb 2021 16:55:04

US3492117

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:31
User entered 'Left Arm (LEFT ARM)'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:55:04

US3492117

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:48:31
User entered 'ONCE'	System	26 Feb 2021 16:55:04

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 16:55:04

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:46
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	26 Feb 2021 16:53:24

US3492117

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'I'	System	26 Feb 2021 16:53:24

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 15:30:05

US3492117

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:57
User entered '04 Mar 2021'	(b) (4), (b) (6)	04 Mar 2021 15:30:05

US3492117

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Mar 2021 15:30:05

US3492117

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:48:57
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 15:30:05

US3492117

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:49:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 15:30:14

US3492117

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:58:31
User entered 'I'	System	04 Mar 2021 15:30:14

US3492117

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:50:16

US3492117

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '26 Mar 2021'	Diana Bahena (b) (4)	26 Mar 2021 16:50:16

US3492117

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered 'Clinic (Clinic)'	Diana Bahena (b) (4)	26 Mar 2021 16:50:16

US3492117

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User entered 'OLD57'	System	26 Mar 2021 16:50:16

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:51:15

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '26 Mar 2021'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:51:15
	(b) (4)	

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '11:35'	(b) (4) Diana Bahena (b) (4) (b) (4)	26 Mar 2021 16:51:15

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User entered '26 Mar 2021 11:35'	System	26 Mar 2021 16:51:15

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '98.6' F	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:51:15

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered 'Other (Other)'	Diana Bahena (b) (4)	26 Mar 2021 16:51:15

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered 'tympanic'	(b) (4) Diana Bahena (b) (4) (b) (4)	26 Mar 2021 16:51:15

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '69'	Diana Bahena (b) (4)	26 Mar 2021 16:51:15

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User entered 'bpm'	System	26 Mar 2021 16:51:15

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '18'	Diana Bahena (b) (4)	26 Mar 2021 16:51:15

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User entered 'breaths/min'	System	26 Mar 2021 16:51:15

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '143'	(b) (4) Diana Bahena (b) (4) (b) (4)	26 Mar 2021 16:51:15

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User entered 'mmHg'	System	26 Mar 2021 16:51:15

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '76'	Diana Bahena (b) (4)	26 Mar 2021 16:51:15

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User entered 'mmHg'	System	26 Mar 2021 16:51:15

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31

US3492117

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31

US3492117

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:51:28

US3492117

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '26 Mar 2021'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:51:28

US3492117

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:51:43

US3492117

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '26 Mar 2021'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:51:43
	(b) (4)	

US3492117

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:32
User entered '11:35'	(b) (4) Diana Bahena (b) (4)	26 Mar 2021 16:51:43

US3492117

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:31
User entered '26 Mar 2021 11:35'	System	26 Mar 2021 16:51:43

US3492117

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:51:43

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:55:38
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 117, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 12:36:36
Query 'Per DM CLR: Per Safety Follow Up Diary Day 117, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'No documentation of symptoms or provider contact seen in Safety Follow Up Diary Day 117' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	09 Apr 2021 16:23:08
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 117, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 05:06:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:43
User entered 'Yes (Y)'	Addis Mekonnen (b) (4) (b) (4)	23 Sep 2020 14:46:45

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:31:39
User entered	System	28 Sep 2020 14:31:28
'USA-US101-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	28 Sep 2020 14:31:28

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
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) (b) (4)	27 Sep 2020 04:22:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Sep 2020 04:22:39
Data point term sent to Coder	System	26 Sep 2020 19:08:54
User entered 'Covid 19, Confirmed'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered 'Yes (Y)'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered 'No (N)'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered 'Yes (Y)'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered '22 Sep 2020'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered empty.	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	01 Nov 2020 21:12:56
User entered 'No (N)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:12:56
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	01 Nov 2020 21:12:42
User entered 'Yes (Y)'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 19:38:47
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved). ' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 23:54:22
Query 'PV Query: Please provide the event end date (when symptoms have resolved). ' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4)	01 Nov 2020 21:14:29
User entered '5 Oct 2020' reason for change: New Information	Andrea Wendrow (b) (4)	01 Nov 2020 21:12:42
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved). ' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 19:02:43
User entered empty.	Richard Novak (b) (4)	26 Sep 2020 19:08:07
	(b) (4)	

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered empty.	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered 'No (N)'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered '0'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered '0'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered '0'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered empty.	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered empty.	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered empty.	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered empty.	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered '0'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered '0'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered '0'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	26 Sep 2020 19:19:43
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	26 Sep 2020 19:08:07
User entered 'Not Related (NOT RELATED)'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered 'Not Related (NOT RELATED)'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 23:53:59
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 15:48:10
User closed query 'Per CDM: Please confirm IP Withdrawn. If confirmed, please complete dosing discontinuation page under EOS folder. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:47:49
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 infection' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:15:03
Query 'Per CDM: Please confirm IP Withdrawn. If confirmed, please complete dosing discontinuation page under EOS folder. ' answered with 'confirmed' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:14:49
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 'correct, will not receive D29 dose' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:14:43
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	29 Oct 2020 23:11:56
User opened query 'Per CDM: Please confirm IP Withdrawn. If confirmed, please complete dosing discontinuation page under EOS folder. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:22:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	23 Oct 2020 15:22:47
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)	02 Oct 2020 19:02:58
User entered 'None (NONE)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	26 Sep 2020 19:19:43
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered '0'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered 'I'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered '0'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 19:38:47
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)	02 Nov 2020 23:54:34
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 21:15:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Andrea Wendrow (b) (4)	01 Nov 2020 21:12:42
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)	02 Oct 2020 19:03:12
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Richard Novak (b) (4)	26 Sep 2020 19:08:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[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 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered empty.	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User closed query 'Per DM CLR: SAE Narrative = SHE TOOK TYLENOL WITH SOME RELEIF OF HER FEVER AND MYALGIAS. However, Tylenol indication in CM eCRF is fever and headache. Please review and reconcile data among eCRF pages as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:17:47
User closed query 'Per DM CLR: SAE Narrative = PARTICIPANT TOOK IBUPROFEN 800MG. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:17:31
Query 'Per DM CLR: SAE Narrative = SHE TOOK TYLENOL WITH SOME RELEIF OF HER FEVER AND MYALGIAS. However, Tylenol indication in CM eCRF is fever and headache. Please review and reconcile data among eCRF pages as appropriate.' answered with 'UPDATED' (Site from DM).	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 17:17:53
Query 'Per DM CLR: SAE Narrative = PARTICIPANT TOOK IBUPROFEN 800MG. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'UPDATED' (Site from DM).	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 17:17:34
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:47
User opened query 'Per DM CLR: SAE Narrative = SHE TOOK TYLENOL WITH SOME RELEIF OF HER FEVER AND MYALGIAS. However, Tylenol indication in CM eCRF is fever and headache. Please review and reconcile data among eCRF pages as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:57:55
User opened query 'Per DM CLR: SAE Narrative = PARTICIPANT TOOK IBUPROFEN 800MG. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:57:48
User closed query 'PV Query: Please fill out the COVID-19 assessment page for 22, 24 and 25 Sep 2020. ' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 23:54:55

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify symptom reported as "choriza". ' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 23:53:18
Query 'PV Query: Please clarify symptom reported as "choriza".	Andrea Wendrow (b) (4)	01 Nov 2020 21:15:25
' answered with 'choriza is the medical term for common cold, usually spelled coryza' (Site from Safety).	(b) (4)	
Query 'PV Query: Please fill out the COVID-19 assessment page for 22, 24 and 25 Sep 2020. ' answered with 'please clarify' (Site from Safety).	Andrea Wendrow (b) (4)	01 Nov 2020 21:15:20
User opened query 'PV Query: Please clarify symptom reported as "choriza".	(b) (4), (b) (6)	02 Oct 2020 19:03:43
' (Site from Safety).		
User opened query 'PV Query: Please fill out the COVID-19 assessment page for 22, 24 and 25 Sep 2020. ' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 19:03:25

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Narrative](#)

Audit	User	Time (GMT)
User entered 'The participant called the call center on 9/23/2020 indicating she had fever and myalgias of her upper extremities, sore throat, choriza and cough which began on 9/22/2020. I decided this would trigger an illness visit. We sent the mobile team to assess her and collect samples. They indicated the participant took Ibuprofen 800mg with minimal relief. The NP swab collected on 9/23/2020 was sent to Viracor. The results came back on 9/26 as positive. The participant called me on 9/23 reporting a temperature exceeding 101 and more severe myalgias. She denied SOB. I went with the mobile team to her home to assess her on 9/24. At that time, she reported that she cares for her elderly parents, and saw one of her brothers who recently returned from Mexico with an illness. No one else was sick. Her symptoms began on 9/22, and had worsened by today, but after I spoke to her by phone, she took tylenol with some releif of her fever and myalgias. On my exam that day, she was in no distress, temp 98.0, pulse Ox 100%, pulse 84. Her lungs were clear on exam. I advised her to continue tylenol every 4-6 hours PRN. The NP collected another NP swab for local processing for COVID19, and another for respiratory virus panel. I again called her on 9/26 and she reported that in the preceding 24 hours, she was feeling better, but did develop anosmia and ageusia. She also reported that now her husband had symptoms of fever and myalgias.'	Richard Novak (b) (4)	26 Sep 2020 19:08:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Sep 2020 19:08:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Sep 2020 19:08:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:51:43

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:55:38
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 22:04:38
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:33:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 16:37:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 16:37:34
Data point term sent to Coder	System	09 Nov 2020 16:37:09
Coding entries removed.	Diana Bahena (b) (4)	09 Nov 2020 16:36:32
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 22:08:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 22:08:42
Data point term sent to Coder	System	24 Sep 2020 22:07:48
User entered 'Tylenol'	Elena Llinas (b) (4)	24 Sep 2020 22:06:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'No (N)'	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 22:06:55

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Un-verified.	Diana Bahena (b) (4)	09 Nov 2020 16:36:32
User entered 'FEVER, MYALGIAS AND HEADACHE' reason for change: Data Entry Error	Diana Bahena (b) (4)	09 Nov 2020 16:36:32
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Fever and headache'	Elena Llinas (b) (4)	24 Sep 2020 22:06:55

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
Signature has been broken.	Andrea Wendrow (b) (4)	12 Mar 2021 12:49:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '1000'	Elena Llinas (b) (4)	24 Sep 2020 22:06:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'mg (mg)'	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 22:06:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 22:06:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'as needed (PRN)'	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 22:06:55

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:44:14
Signature has been broken.	Andrea Wendrow (b) (4)	12 Mar 2021 12:50:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Elena Llinas (b) (4)	24 Sep 2020 22:06:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Oral (ORAL)'	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 22:06:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 22:06:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '24 Sep 2020'	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 22:06:55

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '0'	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 22:06:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'No (N)'	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 22:06:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '24 Sep 2020'	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 22:06:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER AND HEADACHE in eDiary. Please note that this CM was given after Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:16:21
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER AND HEADACHE in eDiary. Please note that this CM was given after Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' answered with 'This was not taken for a solicited event' (Site from DM).	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 16:36:50
DataPoint Un-verified.	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 16:36:32
User entered 'No (N)' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 16:36:32
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER AND HEADACHE in eDiary. Please note that this CM was given after Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:22:41
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 22:06:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User entered empty.	System	24 Sep 2020 22:06:55

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User entered empty.	System	24 Sep 2020 22:06:55

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:00
User entered empty.	System	24 Sep 2020 22:06:55

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:46:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:46:30
Data point term sent to Coder	System	01 Nov 2020 21:22:33
Coding entries removed.	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:22:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 05:12:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 05:12:52
Data point term sent to Coder	System	02 Oct 2020 21:21:58
User entered 'Pseudoephedrine, 30mg x 1'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'No (N)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'SINUS CONGESTION from COVID-19 infection' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Nov 2020 21:22:21
User entered 'sinus congestion'	Richard Novak (b) (4)	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '30'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'mg (mg)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'once (ONCE)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Oral (ORAL)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '1 Oct 2020'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '0'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'No (N)'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '1 Oct 2020'	Richard Novak (b) (4) (b) (4)	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SINUS CONGESTION is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SINUS CONGESTION did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:49:12
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SINUS CONGESTION is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SINUS CONGESTION did not meet the AE reporting criteria. ' answered with 'sinus congestion from covid infection' (Site from DM).	Andrea Wendrow (b) (4)	01 Nov 2020 21:22:36
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Nov 2020 21:21:28

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User entered empty.	System	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User entered empty.	System	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:05
User entered empty.	System	02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:25:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:25:21
Data point term sent to Coder	System	20 Oct 2020 21:24:40
User entered 'Vitamin D'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 02:12:56
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Lorna Sanchez McCann (b) (4)	06 Nov 2020 17:49:12
User entered 'Yes (Y)' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	06 Nov 2020 17:49:02
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:23:15
User entered 'No (N)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Supplement'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '2000'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'IU (IU)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'once daily (QD)' reason for change:	Diana Bahena (b) (4)	20 Oct 2020 21:24:37
Data Entry Error	(b) (4)	
User entered 'other (OTHER)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	20 Oct 2020 21:24:37
User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	20 Oct 2020 21:24:06
User entered empty.	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Oral (ORAL)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'un UNK 2015'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '0'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'No (N)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:24:37
User entered empty.	System	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:24:37
User entered empty.	System	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:24:37
User entered empty.	System	20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:26:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:26:25
Data point term sent to Coder	System	20 Oct 2020 21:25:41
User entered 'Zinc'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 02:13:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Lorna Sanchez McCann (b) (4)	06 Nov 2020 17:48:16
User entered 'Yes (Y)' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	06 Nov 2020 17:48:05
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:23:35
User entered 'No (N)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Supplement'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '50'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'mg (mg)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'once daily (QD)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Oral (ORAL)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'un UNK 2015'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '0'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'No (N)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 17:50:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 17:50:22
Data point term sent to Coder	System	06 Nov 2020 17:48:50
Coding entries removed.	Lorna Sanchez McCann (b) (4)	06 Nov 2020 17:48:39
User entered 'Multivitamins' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	06 Nov 2020 17:48:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:29:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:29:29
Data point term sent to Coder	System	20 Oct 2020 21:28:48
User entered 'MVI'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 02:13:09
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Lorna Sanchez McCann (b) (4)	06 Nov 2020 17:48:49
User entered 'Yes (Y)' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	06 Nov 2020 17:48:39
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:24:02
User entered 'No (N)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Supplement'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'I'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'tablet (TABLET)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'once daily (QD)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Oral (ORAL)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'un UNK 2015'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '0'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'No (N)'	Diana Bahena (b) (4) (b) (4)	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 21:54:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 21:54:59
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	12 Jan 2021 20:38:46 12 Jan 2021 20:38:43
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 21:50:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 21:50:37
Data point term sent to Coder User entered 'Ibuprofen'	System Diana Bahena (b) (4)	09 Nov 2020 17:15:12 09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	Diana Bahena (b) (4)	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 11:32:40
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with '-----thank you. corrected.-----' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 20:39:15
User entered 'COIVD-19 (confirmed) - MYALGIAS, FEVER' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 20:38:43
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:06:37
User entered 'Myalgias, Fever'	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '800'	Diana Bahena (b) (4)	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'mg (mg)'	Diana Bahena (b) (4)	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Diana Bahena (b) (4)	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'as needed (PRN)'	Diana Bahena (b) (4)	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Diana Bahena (b) (4)	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Oral (ORAL)'	Diana Bahena (b) (4)	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Diana Bahena (b) (4)	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '23 Sep 2020'	Diana Bahena (b) (4)	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Diana Bahena (b) (4)	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)' reason for change: New Information	Nia Moragne-O'Neal (b) (4)	05 Feb 2021 16:18:57
User entered 'Yes (Y)'	Diana Bahena (b) (4)	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '27 Sep 2020' reason for change: New Information	Nia Moragne-O'Neal (b) (4)	05 Feb 2021 16:18:57
User entered empty.	Diana Bahena (b) (4)	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:31:14
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification.' answered with '-----thank you. corrected.-----' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 20:39:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 20:38:43
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:07:14
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = No. However, this is one of the protocol identified Solicited Adverse Event that fits within reporting timeframe and no entry in the diary was noted. Please review if the response in this field should reflect Solicited AE. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 06:58:57
Query 'Per DM CLR: Was this medication taken for solicited event?' = No. However, this is one of the protocol identified Solicited Adverse Event that fits within reporting timeframe and no entry in the diary was noted. Please review if the response in this field should reflect Solicited AE. Update as appropriate. Otherwise, provide clarification.' answered with 'changed to "yes" as per query prompt' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 19:28:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 19:27:40

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = No. However, this is one of the protocol identified Solicited Adverse Event that fits within reporting timeframe and no entry in the diary was noted. Please review if the response in this field should reflect Solicited AE. Update as appropriate. Otherwise, provide clarification.' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	04 Dec 2020 14:21:17
	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User entered empty.	System	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User entered empty.	System	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:26:24
User entered empty.	System	09 Nov 2020 17:14:44

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 12:15:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 12:15:27
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:47:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 04:10:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 04:10:41
Data point term sent to Coder	System	09 Nov 2020 17:17:15
User entered 'Hydrocodone and acetaminophen'	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	Diana Bahena (b) (4)	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Myalgias'	Diana Bahena (b) (4)	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '5/325'	Diana Bahena (b) (4)	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'mg (mg)'	Diana Bahena (b) (4)	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Diana Bahena (b) (4)	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'once (ONCE)'	Diana Bahena (b) (4)	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Diana Bahena (b) (4)	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Oral (ORAL)'	Diana Bahena (b) (4)	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	Diana Bahena (b) (4)	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '22 Sep 2020'	Diana Bahena (b) (4)	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '0'	Diana Bahena (b) (4)	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'No (N)'	Diana Bahena (b) (4)	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '22 Sep 2020'	Diana Bahena (b) (4)	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 11:32:50
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification.' answered with '-----thank you. corrected.-----' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 20:40:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 20:40:53
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:08:05
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = No. However, this is one of the protocol identified Solicited Adverse Event that fits within reporting timeframe and no entry in the diary was noted. Please review if the response in this field should reflect Solicited AE. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 07:01:07
Query 'Per DM CLR: Was this medication taken for solicited event?' = No. However, this is one of the protocol identified Solicited Adverse Event that fits within reporting timeframe and no entry in the diary was noted. Please review if the response in this field should reflect Solicited AE. Update as appropriate. Otherwise, provide clarification.' answered with 'changed to "yes" as per query prompt' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 19:29:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 19:29:03

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = No. However, this is one of the protocol identified Solicited Adverse Event that fits within reporting timeframe and no entry in the diary was noted. Please review if the response in this field should reflect Solicited AE. Update as appropriate. Otherwise, provide clarification.' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	04 Dec 2020 14:21:44
	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User entered empty.	System	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User entered empty.	System	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:11
User entered empty.	System	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: BILE ACID SEQUESTRANTS, PRODUCT: COLESEVELAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Jan 2021 14:47:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Jan 2021 14:47:40
Data point term sent to Coder	System	07 Jan 2021 14:46:39
User entered 'Colesevelam'	Ian Feather (b) (4) (b) (4)	07 Jan 2021 14:45:56

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
	(b) (4)	
User entered 'No (N)'	Ian Feather (b) (4)	07 Jan 2021 14:45:56
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
	(b) (4)	
User entered 'hyperlipidemia'	Ian Feather (b) (4)	07 Jan 2021 14:45:56
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
	(b) (4)	
User entered '1250'	Ian Feather (b) (4)	07 Jan 2021 14:45:56
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
	(b) (4)	
User entered 'mg (mg)'	Ian Feather (b) (4)	07 Jan 2021 14:45:56
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
	(b) (4)	
User entered empty.	Ian Feather (b) (4)	07 Jan 2021 14:45:56
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
	(b) (4)	
User entered 'twice daily (BID)'	Ian Feather (b) (4)	07 Jan 2021 14:45:56
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
	(b) (4)	
User entered empty.	Ian Feather (b) (4)	07 Jan 2021 14:45:56
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
	(b) (4)	
User entered 'Oral (ORAL)'	Ian Feather (b) (4)	07 Jan 2021 14:45:56
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
	(b) (4)	
User entered empty.	Ian Feather (b) (4)	07 Jan 2021 14:45:56
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
	(b) (4)	
User entered '23 Dec 2020'	Ian Feather (b) (4)	07 Jan 2021 14:45:56
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
	(b) (4)	
User entered '0'	Ian Feather (b) (4)	07 Jan 2021 14:45:56
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
	(b) (4)	
User entered 'Yes (Y)'	Ian Feather (b) (4)	07 Jan 2021 14:45:56
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
	(b) (4)	
User entered empty.	Ian Feather (b) (4)	07 Jan 2021 14:45:56
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
	(b) (4)	
User entered 'No (N)'	Ian Feather (b) (4)	07 Jan 2021 14:45:56
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Jan 2021 14:45:56

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Jan 2021 14:45:56

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Jan 2021 14:45:56

US3492117

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:51:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:39:06
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:33:10

US3492117

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:51:43

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:25:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '26 Sep 2020'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 23:11:56

US3492117

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:51:43

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:25:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered 'Due to SARS-COV-2 (COVID)'	Andrea Wendrow (b) (4)	29 Oct 2020 23:11:56

US3492117

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:25:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 23:11:56

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'USA-US101-2020-MRNA-1273-P301000001'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'Richard'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'Novak'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered '808 S. Wood St'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'Chicago'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'IL'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered '60612'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 23:55:23
User entered 'US'	System	28 Sep 2020 14:32:33

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
User entered '2'	(b) (4)	02 Nov 2020 23:55:35
User entered '1'	System	28 Sep 2020 14:32:33

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'USA-US101-2020-MRNA-1273-P301000001'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'Richard'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'Novak'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered '808 S. Wood St'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'Chicago'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'IL'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered '60612'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 23:55:23
User entered 'US'	System	28 Sep 2020 14:32:33

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
	(b) (4)	
User entered '2'	System	02 Nov 2020 23:55:35
User entered '1'	System	28 Sep 2020 14:32:33

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:51:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
User entered '28/Sep/2020 14:32'	System	28 Sep 2020 14:32:33

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:51:43

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 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 23:55:23
User entered 'I'	(b) (4), (b) (6)	28 Sep 2020 14:32:33

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'USA-US101-2020-MRNA-1273-P301000001'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'No (N)'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'Richard'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'Novak'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered '808 S. Wood St'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'Chicago'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered 'IL'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:32:03
User entered '60612'	System	28 Sep 2020 14:31:28

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 23:55:23
User entered 'US'	System	28 Sep 2020 14:32:33

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
	(b) (4)	
User entered '2'	System	02 Nov 2020 23:55:35
User entered '1'	System	28 Sep 2020 14:32:33

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:51:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
User entered '02/Nov/2020 18:55'	System	02 Nov 2020 23:55:35

US3492117

Folder: SAE USA-US101-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:51:43

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 03:47:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:38:23
User entered 'I'	(b) (4), (b) (6)	02 Nov 2020 23:55:35