

US3492117 (Prod: UIC Project WISH CRS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:29:39

All time stamps listed in this document are displayed in GMT

US3492117

Form: Participant Creation

Generated On: 26 Nov 2020 09:29:39

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:39

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
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

Generated On: 26 Nov 2020 09:29:39

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 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:29:39

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:29:39

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:39

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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: Vital Signs

Generated On: 26 Nov 2020 09:29:39

Were vital signs assessed?	Yes ☒
	No ☐
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 ☐
	Axillary ☐
	Other ☒
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

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

Date of assessment (<i>dd MMM yyyy</i>)	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 (<i>dd MMM yyyy</i>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2007
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

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

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

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Folder: Screening

Form: Risk of Exposure

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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

Generated On: 26 Nov 2020 09:29:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
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 ☐ Axillary ☐ Other ☒
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)

Generated On: 26 Nov 2020 09:29:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
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 ☐ Axillary ☐ Other ☒
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

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

Collection date (<i>dd MMM yyyy</i>)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	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

Generated On: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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 ☒

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:39

Yes ☐	
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: 26 Nov 2020 09:29:39

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 ☒

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:39

Yes ☐	
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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

Yes ☐	
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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

Yes ☐	
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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

Yes ☐	
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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

Yes ☐	
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

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

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 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	8 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
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 ☐
	Axillary ☐
	Other ☒
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)

Generated On: 26 Nov 2020 09:29:39

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

US3492117

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	8 OCT 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492117

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	6 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

Were vital signs assessed?	Yes ☒
	No ☐
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 ☐
	Axillary ☐
	Other ☒
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

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	6 NOV 2020
Collection time (<i>00:00-23:59</i>)	11:20 (24 HR)
Collection date and time (derived)	6 NOV 2020 11:20

US3492117

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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 ☒

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 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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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: 26 Nov 2020 09:29:39

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

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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: 26 Nov 2020 09:29:39

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

[Patient Cloud Close Date & Time](#)

18 NOV 2020 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 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: 26 Nov 2020 09:29:39

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

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

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13 JAN 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

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

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27 JAN 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

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

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03 FEB 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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10 FEB 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

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Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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24 FEB 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT

DAY 173

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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03 MAR 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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10 MAR 2021 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 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: 26 Nov 2020 09:29:39

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 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: 26 Nov 2020 09:29:39

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 09:29:39

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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°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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

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26 JAN 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

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02 FEB 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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05 FEB 2022 00:01

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09 FEB 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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12 FEB 2022 00:01

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16 FEB 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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

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

Date and time of submission

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23 FEB 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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12 MAR 2022 00:01

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16 MAR 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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19 MAR 2022 00:01

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23 MAR 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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

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30 MAR 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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

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06 APR 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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16 APR 2022 00:01

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20 APR 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

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

Date and time of submission

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23 APR 2022 00:01

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27 APR 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 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: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 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: 26 Nov 2020 09:29:39

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT

DAY 684

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

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

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

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

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

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

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: 26 Nov 2020 09:29:39

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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

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

Date and time of submission

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06 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: 26 Nov 2020 09:29:39

TIMEPOINT

DAY 705

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

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

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

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

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

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

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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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17 AUG 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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24 AUG 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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07 SEP 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

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

Date and time of submission

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14 SEP 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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28 SEP 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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05 OCT 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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12 OCT 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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19 OCT 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

Date and time of submission

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26 OCT 2022 23:59

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:39

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 ☐ 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: 26 Nov 2020 09:29:39

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

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3492117

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

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 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:39

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	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☒
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:39

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	22 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	297 of 1922	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:39

	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: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	100.7 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	301 of 1922	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

	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: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	25 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	305 of 1922	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

	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: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:39

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	26 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	309 of 1922	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:39

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:39

	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: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	27 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	313 of 1922	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:39

	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: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	28 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	101.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	317 of 1922	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

	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: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	29 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	321 of 1922	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

	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: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	30 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.7 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	325 of 1922	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

	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: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	01 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	329 of 1922	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

	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: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	02 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	100.0 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	333 of 1922	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

	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: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	24 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	337 of 1922	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

	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: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☒
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	3 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	102.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	341 of 1922	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

	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: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☒
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	4 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	102.0 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	345 of 1922	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

	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: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☒
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	5 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	101.0 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	349 of 1922	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

	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

Generated On: 26 Nov 2020 09:29:39

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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

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 _____

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

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

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 _____

Hepatic Dysfunction? Yes ☐ No ☒

Start Date _____

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

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

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:29:39

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☒
	Clinic ☐
Folder OID	SICKD1

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	23 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:20 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 12:20
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	100.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	20 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD28

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

Were vital signs assessed?	Yes ☒
	No ☐
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 ☐
	Axillary ☐
	Other ☒
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

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

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: Unscheduled 23 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:29:39

Visit Date

Please check all assessments that apply for this visit

Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	False

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:39

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

Was the sample collected?

Yes ☐

No ☐

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3492117

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:29:39

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)

Generated On: 26 Nov 2020 09:29:39

AEID	USA-US101-2020-MRNA-1273-P30 1000001
Adverse event	COVID 19, CONFIRMED
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☒ No ☐
Start date (dd MMM yyyy)	22 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	5 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	371 of 1922

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

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

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

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
HER BY PHONE, SHE TOOK
TYLENOL WITH SOME RELEIF

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

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)

Generated On: 26 Nov 2020 09:29:39

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

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:39

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

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:39

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 ☐ Intraocular ☐

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:39

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	1 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		1 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:39

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 ☐ Intramuscular ☐

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:39

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 ☐ Intramuscular ☐

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:39

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

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:39

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 ☐ Intramuscular ☐

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:39

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	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 ☐ Intraocular ☐ Intramuscular ☐

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		23 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:39

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 ☐ Intraocular ☐

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:39

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		22 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3492117

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

Visit	Screening	☐
	Visit 1 Day 1	☐
	Visit 2 Day 29	☐
	Visit 3 Day 57	☐
	Visit 4 Day 209	☐
	Visit 5 Day 394	☐
	Visit 6 Day 759	☐

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: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

Date of dosing discontinuation (dd MMM yyyy)

26 SEP 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☒

Other ☐

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

US3492117

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:29:39

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

Generated On: 26 Nov 2020 09:29:39

SAEID	USA-US101-2020-MRNA-1273-P301000001
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:39

SAEID	USA-US101-2020-MRNA-1273-P301000001
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:39

SAEID	USA-US101-2020-MRNA-1273-P301000001
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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: 26 Nov 2020 09:29:39

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3492117'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Sep 2020 18:45:09

US3492117

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:23:14

US3492117

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Sep 2020 18:45:10

US3492117

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:23:14

US3492117

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	10 Sep 2020 19:23:14

US3492117

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:39

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1959'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Sep 2020 18:45:11

US3492117

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:39

[Age](#)

Audit	User	Time (GMT)
User entered '61'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:39

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '61'	System	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:39

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:02
	(b) (4)	

US3492117

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:39

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:39

White

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:39

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:39

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:39

[Other](#)

Audit	User	Time (GMT)
User entered '1'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:39

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered 'Hispanic'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:39

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:39

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:24:02

US3492117

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:39

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:22
	(b) (4)	

US3492117

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '2020'	System	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:39

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Nusirat Williams (b) (4)	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:24:22

US3492117

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Sep 2020 18:45:10

US3492117

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 19:24:29

US3492117

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:24:29

US3492117

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:29:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: 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.	(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
	(b) (4)	

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered 'un UNK 2007'	Gizelle Alvarez (b) (4) (b) (4)	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Gizelle Alvarez (b) (4) (b) (4)	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Gizelle Alvarez (b) (4) (b) (4)	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '2007'	System	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:14:56

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	10 Sep 2020 19:25:45
	(b) (4)	

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Nusirat Williams (b) (4)	10 Sep 2020 19:25:45
	(b) (4)	

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '13:50'	Nusirat Williams (b) (4)	10 Sep 2020 19:25:45
	(b) (4)	

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 13:50'	System	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '147' cm	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: 26 Nov 2020 09:29:39

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '52.9' kg	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: 26 Nov 2020 09:29:39

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4)	10 Sep 2020 19:25:45
	(b) (4)	

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4)	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 19:25:45

US3492117

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	10 Sep 2020 19:26:00
	(b) (4)	

US3492117

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Nusirat Williams (b) (4)	10 Sep 2020 19:26:00
	(b) (4)	

US3492117

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:39

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Nusirat Williams (b) (4)	10 Sep 2020 19:28:20
	(b) (4)	

US3492117

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:28:20
	(b) (4)	

US3492117

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:39

If No, what is the reason?

Audit	User	Time (GMT)
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) (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)	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)	10 Sep 2020 19:28:20

US3492117

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:39

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:28:20

US3492117

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:28:20

US3492117

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:39

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:28:20

US3492117

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered 'UN UNK 2007'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:28:20

US3492117

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:39

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:28:20

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32
	(b) (4)	

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32
	(b) (4)	

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

[Warehouse shipping and fulfillment centers](#) and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32
	(b) (4)	

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32
	(b) (4)	

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32
	(b) (4)	

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32
	(b) (4)	

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32
	(b) (4)	

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32
	(b) (4)	

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

[Specify](#)

Audit	User	Time (GMT)
User entered 'Not employed'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32
	(b) (4)	

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32
	(b) (4)	

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '1'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32
	(b) (4)	

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32
	(b) (4)	

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:32
	(b) (4)	

US3492117

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:39

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:29:32

US3492117

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:29:47

US3492117

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:29:47

US3492117

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Nusirat Williams (b) (4)	10 Sep 2020 19:29:47
	(b) (4)	

US3492117

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	10 Sep 2020 19:29:47

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Sep 2020 19:10:00

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '112999'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Sep 2020 19:10:00

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Sep 2020 19:10:00

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:39

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:30:46

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:39

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:30:46

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:39

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:30:46

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:30:46

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:39

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:30:46

US3492117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(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: 26 Nov 2020 09:29:39

Height

Audit	User	Time (GMT)
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) (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)	19 Oct 2020 15:50:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(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)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:39

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4)	19 Oct 2020 15:50:34
User entered '52.9' kg	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:39

Height

Audit	User	Time (GMT)
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) (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)	19 Oct 2020 15:50:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(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)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:39

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4)	19 Oct 2020 15:50:34
User entered '52.9' kg	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '13:50'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '99' F	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Ear'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '16'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '142'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '92'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:39

Height

Audit	User	Time (GMT)
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) (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)	19 Oct 2020 15:50:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(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)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:39

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4)	19 Oct 2020 15:50:34
User entered '52.9' kg	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 20:00:48
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).	System	10 Sep 2020 19:32:11
User entered empty.	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020' reason for change: Data Entry Error	Nusirat Williams (b) (4)	10 Sep 2020 20:00:48
User entered empty.	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '14:55' reason for change: Data Entry Error	Nusirat Williams (b) (4)	10 Sep 2020 20:00:48
User entered empty.	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 14:55'	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: 26 Nov 2020 09:29:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.5' C reason for change: Data Entry Error	Nusirat Williams (b) (4)	10 Sep 2020 20:00:48
User entered empty.	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data Nusirat Williams Entry Error	(b) (4)	10 Sep 2020 20:00:48
User entered empty.	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Ear' reason for change: Data Entry Error	Nusirat Williams (b) (4)	10 Sep 2020 20:00:48
User entered empty.	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63' reason for change: Data Entry Error	Nusirat Williams (b) (4)	10 Sep 2020 20:00:48
User entered empty.	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	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: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '18' reason for change: Data Entry Error	Nusirat Williams (b) (4)	10 Sep 2020 20:00:48
User entered empty.	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	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: 26 Nov 2020 09:29:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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) (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

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '92' reason for change: Data Entry Error	Nusirat Williams (b) (4)	10 Sep 2020 20:00:48
User entered empty.	Nusirat Williams (b) (4)	10 Sep 2020 19:32:11

US3492117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:20

US3492117

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:20

US3492117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:59:02

US3492117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:59:02

US3492117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4)	10 Sep 2020 19:59:02
	(b) (4)	

US3492117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 19:59:02

US3492117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Nusirat Williams (b) (4)	10 Sep 2020 19:59:02
	(b) (4)	

US3492117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:48'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:59:02

US3492117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 14:48'	System	10 Sep 2020 19:59:02

US3492117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	10 Sep 2020 19:59:02

US3492117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 19:59:02

US3492117

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	10 Sep 2020 19:45:39

US3492117

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Gizelle Alvarez (b) (4) (b) (4)	10 Sep 2020 19:45:39

US3492117

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:15'	Gizelle Alvarez (b) (4) (b) (4)	10 Sep 2020 19:45:39

US3492117

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Gizelle Alvarez (b) (4) (b) (4)	10 Sep 2020 19:45:52

US3492117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:39

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	10 Sep 2020 19:45:52

US3492117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:39

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '14:30'	Gizelle Alvarez (b) (4) (b) (4)	10 Sep 2020 19:45:52

US3492117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Gizelle Alvarez (b) (4) (b) (4)	10 Sep 2020 19:45:52

US3492117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	10 Sep 2020 19:45:52

US3492117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 19:45:52

US3492117

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	10 Sep 2020 19:32:38

US3492117

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 19:32:38

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	10 Sep 2020 20:11:18
User entered 'Yes (Y)'	System	10 Sep 2020 20:11:18

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	10 Sep 2020 20:11:18
User entered '97.8'	System	10 Sep 2020 20:11:18

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	10 Sep 2020 20:11:18
User entered '10 Sep 2020 15:11'	System	10 Sep 2020 20:11:18

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	11 Sep 2020 14:12:01
User entered 'Yes (Y)'	System	11 Sep 2020 14:12:01

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	11 Sep 2020 14:12:01
User entered '98.1'	System	11 Sep 2020 14:12:01

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	11 Sep 2020 14:12:01
User entered '11 Sep 2020 09:11'	System	11 Sep 2020 14:12:01

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:11:47
User entered 'Yes (Y)'	System	12 Sep 2020 13:11:47

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:11:47
User entered '98.2'	System	12 Sep 2020 13:11:47

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:11:47
User entered 'No (N)'	System	12 Sep 2020 13:11:47

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:11:47
User entered '12 Sep 2020 08:11'	System	12 Sep 2020 13:11:47

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	13 Sep 2020 13:35:15
User entered 'Yes (Y)'	System	13 Sep 2020 13:35:15

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	13 Sep 2020 13:35:15
User entered 'No (N)'	System	13 Sep 2020 13:35:15

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	13 Sep 2020 13:35:15
User entered '13 Sep 2020 08:35'	System	13 Sep 2020 13:35:15

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	14 Sep 2020 13:26:13
User entered 'Yes (Y)'	System	14 Sep 2020 13:26:13

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	14 Sep 2020 13:26:13
User entered '96.8'	System	14 Sep 2020 13:26:13

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	14 Sep 2020 13:26:13
User entered 'No (N)'	System	14 Sep 2020 13:26:13

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	14 Sep 2020 13:26:13
User entered '14 Sep 2020 08:26'	System	14 Sep 2020 13:26:13

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	15 Sep 2020 12:40:31
User entered 'Yes (Y)'	System	15 Sep 2020 12:40:31

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	15 Sep 2020 12:40:31
User entered '97.9'	System	15 Sep 2020 12:40:31

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	15 Sep 2020 12:40:31
User entered '15 Sep 2020 07:40'	System	15 Sep 2020 12:40:31

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	16 Sep 2020 13:41:19
User entered 'Yes (Y)'	System	16 Sep 2020 13:41:19

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	16 Sep 2020 13:41:19
User entered '98.2'	System	16 Sep 2020 13:41:19

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	16 Sep 2020 13:41:19
User entered 'No (N)'	System	16 Sep 2020 13:41:19

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	16 Sep 2020 13:41:19
User entered '16 Sep 2020 08:41'	System	16 Sep 2020 13:41:19

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	17 Sep 2020 15:00:09
User entered 'Yes (Y)'	System	17 Sep 2020 15:00:09

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	17 Sep 2020 15:00:09
User entered '98.1'	System	17 Sep 2020 15:00:09

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	17 Sep 2020 15:00:09
User entered '17 Sep 2020 10:00'	System	17 Sep 2020 15:00:09

US3492117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

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

Please select one response below

Audit	User	Time (GMT)
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'	System	10 Sep 2020 20:11:57
User entered 'None (1)'	System	10 Sep 2020 20:11:57

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	10 Sep 2020 20:11:57
User entered 'No (N)'	System	10 Sep 2020 20:11:57

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	10 Sep 2020 20:11:57
User entered 'No (N)'	System	10 Sep 2020 20:11:57

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:39

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

Please select one response below

Audit	User	Time (GMT)
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'	System	10 Sep 2020 20:11:57
User entered 'None (1)'	System	10 Sep 2020 20:11:57

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	10 Sep 2020 20:11:57
User entered '10 Sep 2020 15:11'	System	10 Sep 2020 20:11:57

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	11 Sep 2020 14:13:22
User entered 'No (N)'	System	11 Sep 2020 14:13:22

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	11 Sep 2020 14:13:22
User entered 'No (N)'	System	11 Sep 2020 14:13:22

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:39

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	11 Sep 2020 14:13:22
User entered '11 Sep 2020 09:13'	System	11 Sep 2020 14:13:22

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

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

Please select one response below

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:12:17
User entered 'None (1)'	System	12 Sep 2020 13:12:17

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:12:17
User entered 'No (N)'	System	12 Sep 2020 13:12:17

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:12:17
User entered 'No (N)'	System	12 Sep 2020 13:12:17

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:39

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

Please select one response below

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:12:17
User entered 'None (1)'	System	12 Sep 2020 13:12:17

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:12:17
User entered '12 Sep 2020 08:12'	System	12 Sep 2020 13:12:17

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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-a0e5-8dc922b24db'	System	13 Sep 2020 13:35:45
User entered 'No (N)'	System	13 Sep 2020 13:35:45

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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-a0e5-8dc922b24db'	System	13 Sep 2020 13:35:45
User entered 'No (N)'	System	13 Sep 2020 13:35:45

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:39

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

Please select one response below

Audit	User	Time (GMT)
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'	System	13 Sep 2020 13:35:45
User entered 'None (1)'	System	13 Sep 2020 13:35:45

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	14 Sep 2020 13:26:40
User entered 'No (N)'	System	14 Sep 2020 13:26:40

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	14 Sep 2020 13:26:40
User entered 'No (N)'	System	14 Sep 2020 13:26:40

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:39

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	14 Sep 2020 13:26:40
User entered '14 Sep 2020 08:26'	System	14 Sep 2020 13:26:40

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	16 Sep 2020 13:41:49
User entered 'No (N)'	System	16 Sep 2020 13:41:49

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	16 Sep 2020 13:41:49
User entered 'No (N)'	System	16 Sep 2020 13:41:49

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:39

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	16 Sep 2020 13:41:49
User entered '16 Sep 2020 08:41'	System	16 Sep 2020 13:41:49

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	17 Sep 2020 15:00:27
User entered 'No (N)'	System	17 Sep 2020 15:00:27

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	17 Sep 2020 15:00:27
User entered 'No (N)'	System	17 Sep 2020 15:00:27

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:39

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	17 Sep 2020 15:00:27
User entered '17 Sep 2020 10:00'	System	17 Sep 2020 15:00:27

US3492117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

HEADACHE

Audit	User	Time (GMT)
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'	System	10 Sep 2020 20:12:35
User entered 'None (0)'	System	10 Sep 2020 20:12:35

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:39

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	10 Sep 2020 20:12:35
User entered 'None (0)'	System	10 Sep 2020 20:12:35

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:39

CHILLS

Audit	User	Time (GMT)
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'	System	10 Sep 2020 20:12:35
User entered 'None (0)'	System	10 Sep 2020 20:12:35

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	10 Sep 2020 20:12:35
User entered 'No (N)'	System	10 Sep 2020 20:12:35

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	10 Sep 2020 20:12:35
User entered '10 Sep 2020 15:12'	System	10 Sep 2020 20:12:35

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

FATIGUE

Audit	User	Time (GMT)
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'	System	11 Sep 2020 14:14:41
User entered 'None (0)'	System	11 Sep 2020 14:14:41

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	11 Sep 2020 14:14:41
User entered 'None (0)'	System	11 Sep 2020 14:14:41

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	11 Sep 2020 14:14:41
User entered 'None (0)'	System	11 Sep 2020 14:14:41

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	11 Sep 2020 14:14:41
User entered 'None (0)'	System	11 Sep 2020 14:14:41

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:39

CHILLS

Audit	User	Time (GMT)
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'	System	11 Sep 2020 14:14:41
User entered 'None (0)'	System	11 Sep 2020 14:14:41

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	11 Sep 2020 14:14:41
User entered 'No (N)'	System	11 Sep 2020 14:14:41

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	11 Sep 2020 14:14:41
User entered '11 Sep 2020 09:14'	System	11 Sep 2020 14:14:41

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

HEADACHE

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:14:28
User entered 'None (0)'	System	12 Sep 2020 13:14:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:39

FATIGUE

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:14:28
User entered 'None (0)'	System	12 Sep 2020 13:14:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:14:28
User entered 'None (0)'	System	12 Sep 2020 13:14:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:14:28
User entered 'None (0)'	System	12 Sep 2020 13:14:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:14:28
User entered 'None (0)'	System	12 Sep 2020 13:14:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:39

CHILLS

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:14:28
User entered 'None (0)'	System	12 Sep 2020 13:14:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:14:28
User entered 'No (N)'	System	12 Sep 2020 13:14:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	12 Sep 2020 13:14:28
User entered '12 Sep 2020 08:13'	System	12 Sep 2020 13:14:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

HEADACHE

Audit	User	Time (GMT)
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'	System	13 Sep 2020 13:36:13
User entered 'None (0)'	System	13 Sep 2020 13:36:13

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:39

FATIGUE

Audit	User	Time (GMT)
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'	System	13 Sep 2020 13:36:13
User entered 'None (0)'	System	13 Sep 2020 13:36:13

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	13 Sep 2020 13:36:13
User entered 'None (0)'	System	13 Sep 2020 13:36:13

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	13 Sep 2020 13:36:13
User entered 'None (0)'	System	13 Sep 2020 13:36:13

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	13 Sep 2020 13:36:13
User entered 'None (0)'	System	13 Sep 2020 13:36:13

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:39

CHILLS

Audit	User	Time (GMT)
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'	System	13 Sep 2020 13:36:13
User entered 'None (0)'	System	13 Sep 2020 13:36:13

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	13 Sep 2020 13:36:13
User entered 'No (N)'	System	13 Sep 2020 13:36:13

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	13 Sep 2020 13:36:13
User entered '13 Sep 2020 08:36'	System	13 Sep 2020 13:36:13

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

HEADACHE

Audit	User	Time (GMT)
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'	System	14 Sep 2020 13:27:18
User entered 'None (0)'	System	14 Sep 2020 13:27:18

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:39

FATIGUE

Audit	User	Time (GMT)
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'	System	14 Sep 2020 13:27:18
User entered 'None (0)'	System	14 Sep 2020 13:27:18

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	14 Sep 2020 13:27:18
User entered 'None (0)'	System	14 Sep 2020 13:27:18

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	14 Sep 2020 13:27:18
User entered 'None (0)'	System	14 Sep 2020 13:27:18

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	14 Sep 2020 13:27:18
User entered 'None (0)'	System	14 Sep 2020 13:27:18

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:39

CHILLS

Audit	User	Time (GMT)
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'	System	14 Sep 2020 13:27:18
User entered 'None (0)'	System	14 Sep 2020 13:27:18

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	14 Sep 2020 13:27:18
User entered 'No (N)'	System	14 Sep 2020 13:27:18

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	14 Sep 2020 13:27:18
User entered '14 Sep 2020 08:27'	System	14 Sep 2020 13:27:18

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

HEADACHE

Audit	User	Time (GMT)
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'	System	15 Sep 2020 12:41:27
User entered 'None (0)'	System	15 Sep 2020 12:41:27

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:39

FATIGUE

Audit	User	Time (GMT)
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'	System	15 Sep 2020 12:41:27
User entered 'None (0)'	System	15 Sep 2020 12:41:27

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	15 Sep 2020 12:41:27
User entered 'None (0)'	System	15 Sep 2020 12:41:27

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	15 Sep 2020 12:41:27
User entered 'None (0)'	System	15 Sep 2020 12:41:27

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	15 Sep 2020 12:41:27
User entered 'None (0)'	System	15 Sep 2020 12:41:27

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:39

CHILLS

Audit	User	Time (GMT)
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'	System	15 Sep 2020 12:41:27
User entered 'None (0)'	System	15 Sep 2020 12:41:27

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	15 Sep 2020 12:41:27
User entered 'No (N)'	System	15 Sep 2020 12:41:27

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

HEADACHE

Audit	User	Time (GMT)
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'	System	16 Sep 2020 13:42:28
User entered 'None (0)'	System	16 Sep 2020 13:42:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:39

FATIGUE

Audit	User	Time (GMT)
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'	System	16 Sep 2020 13:42:28
User entered 'None (0)'	System	16 Sep 2020 13:42:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	16 Sep 2020 13:42:28
User entered 'None (0)'	System	16 Sep 2020 13:42:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	16 Sep 2020 13:42:28
User entered 'None (0)'	System	16 Sep 2020 13:42:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	16 Sep 2020 13:42:28
User entered 'None (0)'	System	16 Sep 2020 13:42:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:39

CHILLS

Audit	User	Time (GMT)
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'	System	16 Sep 2020 13:42:28
User entered 'None (0)'	System	16 Sep 2020 13:42:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	16 Sep 2020 13:42:28
User entered '16 Sep 2020 08:42'	System	16 Sep 2020 13:42:28

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

HEADACHE

Audit	User	Time (GMT)
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'	System	17 Sep 2020 15:00:55
User entered 'None (0)'	System	17 Sep 2020 15:00:55

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:39

FATIGUE

Audit	User	Time (GMT)
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'	System	17 Sep 2020 15:00:55
User entered 'None (0)'	System	17 Sep 2020 15:00:55

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	17 Sep 2020 15:00:55
User entered 'None (0)'	System	17 Sep 2020 15:00:55

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	17 Sep 2020 15:00:55
User entered 'None (0)'	System	17 Sep 2020 15:00:55

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	17 Sep 2020 15:00:55
User entered 'None (0)'	System	17 Sep 2020 15:00:55

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:39

CHILLS

Audit	User	Time (GMT)
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'	System	17 Sep 2020 15:00:55
User entered 'None (0)'	System	17 Sep 2020 15:00:55

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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'	System	17 Sep 2020 15:00:55
User entered 'No (N)'	System	17 Sep 2020 15:00:55

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	17 Sep 2020 15:00:55
User entered '17 Sep 2020 10:00'	System	17 Sep 2020 15:00:55

US3492117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Addis Mekonnen (b) (4) (b) (4)	17 Sep 2020 22:19:04

US3492117

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Addis Mekonnen (b) (4) (b) (4)	17 Sep 2020 22:19:04

US3492117

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Addis Mekonnen (b) (4) (b) (4)	17 Sep 2020 22:19:04

US3492117

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Addis Mekonnen (b) (4) (b) (4)	17 Sep 2020 22:19:07

US3492117

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:19:07

US3492117

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 21:39:10

US3492117

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 21:39:10

US3492117

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 21:39:10

US3492117

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 21:39:10

US3492117

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	24 Sep 2020 21:39:18

US3492117

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 21:39:18

US3492117

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:25:16

US3492117

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 17:25:16

US3492117

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:25:36

US3492117

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:25:36

US3492117

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:25:36

US3492117

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	08 Oct 2020 17:25:36

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Nusirat Williams (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:29:39

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	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: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '11:55'	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: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	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: 26 Nov 2020 09:29:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'tympanic'	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: 26 Nov 2020 09:29:39

Pulse (xxx)

Audit	User	Time (GMT)
User entered '71'	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: 26 Nov 2020 09:29:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '12'	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: 26 Nov 2020 09:29:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '123'	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4)	08 Oct 2020 17:26:29
	(b) (4)	

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4)	08 Oct 2020 17:26:29
	(b) (4)	

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4)	08 Oct 2020 17:26:29
	(b) (4)	

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 17:26:29

US3492117

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	08 Oct 2020 17:26:37
	(b) (4)	

US3492117

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Nusirat Williams (b) (4)	08 Oct 2020 17:26:37
	(b) (4)	

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

[If No, reason not given](#)

Audit	User	Time (GMT)
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).		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).	System	08 Oct 2020 17:26:48
User entered empty.	Nusirat Williams (b) (4)	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4)	08 Oct 2020 17:26:48
	(b) (4)	

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 17:26:48

US3492117

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:27:16

US3492117

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Nusirat Williams (b) (4)	08 Oct 2020 17:27:16
	(b) (4)	

US3492117

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:10'	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:27:16

US3492117

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Nusirat Williams (b) (4)	08 Oct 2020 17:27:31
	(b) (4)	

US3492117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:39

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	08 Oct 2020 17:27:31
	(b) (4)	

US3492117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:15'	Nusirat Williams (b) (4)	08 Oct 2020 17:27:31
	(b) (4)	

US3492117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	08 Oct 2020 17:27:31
	(b) (4)	

US3492117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4)	08 Oct 2020 17:27:31
	(b) (4)	

US3492117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 17:27:31

US3492117

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	08 Oct 2020 17:27:36

US3492117

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 17:27:36

US3492117

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	23 Oct 2020 15:16:30

US3492117

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Diana Bahena (b) (4) (b) (4)	23 Oct 2020 15:16:30

US3492117

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Diana Bahena (b) (4) (b) (4)	23 Oct 2020 15:16:30

US3492117

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Diana Bahena (b) (4) (b) (4)	23 Oct 2020 15:16:30

US3492117

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	20 Oct 2020 17:16:45

US3492117

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 17:16:45

US3492117

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:27:14

US3492117

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:27:14

US3492117

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:27:14

US3492117

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	20 Oct 2020 21:13:40

US3492117

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:13:40

US3492117

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	20 Oct 2020 21:13:50

US3492117

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:13:50

US3492117

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:26:25

US3492117

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:26:25

US3492117

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:26:25

US3492117

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	06 Nov 2020 17:26:25

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '11:10'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'tympanic'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '16'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '118'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 17:26:58

US3492117

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:27:05

US3492117

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:27:05

US3492117

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:27:14

US3492117

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:27:14

US3492117

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:20'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:27:14

US3492117

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	06 Nov 2020 17:27:18

US3492117

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 17:27:18

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[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: '2020-11-10T08:01:57', 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: 26 Nov 2020 09:29:39

Have you been exposed to someone with 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: '2020-11-10T08:02:13', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: '86186806-b342-44ec-ac9a-5ad7677ca3eb'	System	10 Nov 2020 14:02:31
User entered 'No (N)'	System	10 Nov 2020 14:02:31

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

[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: '2020-11-10T08:02:26', 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: 26 Nov 2020 09:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[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: '2020-11-17T21:06:38', 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: 26 Nov 2020 09:29:39

Have you been exposed to someone with 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: '2020-11-17T21:07:00', 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: 26 Nov 2020 09:29:39

[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: '2020-11-17T21:07:10', User OID: 'PatientReportedOutcome (US3492117)', ODM File OID: 'a413530e-5e82-469b-a9ba-d92761b7a780'	System	18 Nov 2020 03:07:12
User entered '17 Nov 2020 21:07:10'	System	18 Nov 2020 03:07:12

US3492117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

[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 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: 26 Nov 2020 09:29:39

[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 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: 26 Nov 2020 09:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:19:00
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 07:19:00

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

[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 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: 26 Nov 2020 09:29:39

[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 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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[Have you been exposed to someone with 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: 26 Nov 2020 09:29:39

[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' User entered '22 Nov 2020 11:45:46'	System	22 Nov 2020 17:45:51
	System	22 Nov 2020 17:45:51

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

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

US3492117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:39

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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'	Andrea Wendrow (b) (4)	23 Sep 2020 21:27:10

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:39

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:35:55
User entered '10:00'	Andrea Wendrow (b) (4)	23 Sep 2020 21:27:10
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:39

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	23 Sep 2020 21:27:10

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:39

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:35:55
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	23 Sep 2020 21:27:10

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 20:00:41
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	03 Oct 2020 19:59:26
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	26 Sep 2020 19:30:54
User entered 'Day 2 (Day 2)'	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:39

Date

Audit	User	Time (GMT)
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) (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)	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)	03 Oct 2020 20:00:14
User entered '23 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (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)	03 Oct 2020 19:53:51
User entered '22 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (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)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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'	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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'	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:39

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)'	Andrea Wendrow (b) (4)	23 Sep 2020 21:29:18

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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'	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Severe (Severe)' reason for change:	(b) (4)	
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: 26 Nov 2020 09:29:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:38

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:39

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	(b) (4) 03 Oct 2020 20:12:16
User entered 'Day 3 (Day 3)'	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: 26 Nov 2020 09:29:39

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '1'	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 20:57:58

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 20:57:58
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:39

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	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 (4)

Generated On: 26 Nov 2020 09:29:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:16
User entered 'Day 4 (Day 4)'	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: 26 Nov 2020 09:29:39

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Richard Novak (b) (4)	27 Sep 2020 19:04:23
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '96'	Richard Novak (b) (4)	27 Sep 2020 19:04:23

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	27 Sep 2020 19:04:23

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:39

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:39

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	27 Sep 2020 19:04:23

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:39

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:39

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:16
User entered 'Day 5 (Day 5)'	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: 26 Nov 2020 09:29:39

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	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: 26 Nov 2020 09:29:39

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	27 Sep 2020 19:07:05

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:39

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '98.1' F	Richard Novak (b) (4)	27 Sep 2020 19:07:05
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:39

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	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: 26 Nov 2020 09:29:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	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: 26 Nov 2020 09:29:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	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: 26 Nov 2020 09:29:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	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: 26 Nov 2020 09:29:39

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:39

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	27 Sep 2020 19:07:05

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:39

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	27 Sep 2020 19:07:05

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:16
User entered 'Day 6 (Day 6)' reason for change: New Information	Richard Novak (b) (4) (b) (4)	30 Sep 2020 20:46:25
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: 26 Nov 2020 09:29:39

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Richard Novak (b) (4)	27 Sep 2020 19:10:09
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '97' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	28 Sep 2020 21:09:42
User entered empty.	System	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '101.2' F reason for change: New Information	Richard Novak (b) (4)	30 Sep 2020 20:46:25
User entered '98.1' F reason for change: Data Entry Error	Richard Novak (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
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: 26 Nov 2020 09:29:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
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: 26 Nov 2020 09:29:39

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
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: 26 Nov 2020 09:29:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Richard Novak (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	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: 26 Nov 2020 09:29:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
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: 26 Nov 2020 09:29:39

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:39

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
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: 26 Nov 2020 09:29:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
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: 26 Nov 2020 09:29:39

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4)	28 Sep 2020 21:09:42
User entered empty.	Richard Novak (b) (4)	27 Sep 2020 19:10:09

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:16
User entered 'Day 7 (Day 7)'	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: 26 Nov 2020 09:29:39

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	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: 26 Nov 2020 09:29:39

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	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: 26 Nov 2020 09:29:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4)	30 Sep 2020 20:48:27
User entered empty.	Richard Novak (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Richard Novak (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Richard Novak (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Richard Novak (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Richard Novak (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Richard Novak (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Richard Novak (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	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: 26 Nov 2020 09:29:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4)	30 Sep 2020 20:48:27
User entered empty.	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: 26 Nov 2020 09:29:39

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Richard Novak (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4)	30 Sep 2020 20:48:27
User entered empty.	Richard Novak (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4)	30 Sep 2020 20:48:27
User entered empty.	Richard Novak (b) (4)	30 Sep 2020 20:46:25

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:39

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)' reason for change: New Information	Richard Novak (b) (4)	30 Sep 2020 20:48:27
User entered empty.	Richard Novak (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: 26 Nov 2020 09:29:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	03 Oct 2020 20:12:16
User entered 'Day 8 (Day 8)'	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: 26 Nov 2020 09:29:39

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Richard Novak (b) (4)	30 Sep 2020 20:51:03
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Sep 2020 20:51:03

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '99.7' F	Richard Novak (b) (4)	30 Sep 2020 20:51:03
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	30 Sep 2020 20:51:03

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	30 Sep 2020 20:51:03
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	30 Sep 2020 20:51:03

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	30 Sep 2020 20:51:03

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	30 Sep 2020 20:51:03
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	30 Sep 2020 20:51:03
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	30 Sep 2020 20:51:03
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	30 Sep 2020 20:51:03
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	30 Sep 2020 20:51:03
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	30 Sep 2020 20:51:03
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	30 Sep 2020 20:51:03
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	30 Sep 2020 20:51:03
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	30 Sep 2020 20:51:03
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:29:39

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	30 Sep 2020 20:51:03
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)' reason for change:	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:16
Data Entry Error	(b) (4)	
User entered 'Day 9 (Day 9)'	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: 26 Nov 2020 09:29:39

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '96'	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	02 Oct 2020 21:13:16

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '99.2' F	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	02 Oct 2020 21:13:16

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Moderate (Moderate)'	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:39

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	02 Oct 2020 21:13:16
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)' reason for change:	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:16
Data Entry Error	(b) (4)	
User entered 'Day 10 (Day 10)'	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: 26 Nov 2020 09:29:39

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Richard Novak (b) (4)	02 Oct 2020 21:15:17
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '96'	Richard Novak (b) (4)	02 Oct 2020 21:15:17
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	02 Oct 2020 21:15:17

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '100.0' F	Richard Novak (b) (4)	02 Oct 2020 21:15:17
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	02 Oct 2020 21:15:17
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	02 Oct 2020 21:15:17
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	02 Oct 2020 21:15:17
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	02 Oct 2020 21:15:17
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	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: 26 Nov 2020 09:29:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	02 Oct 2020 21:15:17
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	02 Oct 2020 21:15:17
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	02 Oct 2020 21:15:17
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	02 Oct 2020 21:15:17
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	02 Oct 2020 21:15:17
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	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: 26 Nov 2020 09:29:39

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	02 Oct 2020 21:15:17
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	02 Oct 2020 21:15:17
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	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: 26 Nov 2020 09:29:39

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	02 Oct 2020 21:15:17
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '24 Sep 2020'	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '1'	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	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: 26 Nov 2020 09:29:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	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: 26 Nov 2020 09:29:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	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: 26 Nov 2020 09:29:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	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: 26 Nov 2020 09:29:39

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:39

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered empty.	Andrea Wendrow (b) (4)	03 Oct 2020 20:12:56
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	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: 26 Nov 2020 09:29:39

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '3 Oct 2020'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '95'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Oct 2020 20:44:30

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '102.2' F	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Moderate (Moderate)'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	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: 26 Nov 2020 09:29:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:39

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	04 Oct 2020 20:44:30
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	Richard Novak (b) (4) (b) (4)	04 Oct 2020 20:46:46

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Form: Symptom Log (13)

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[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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Form: Symptom Log (13)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '96'	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Oct 2020 20:46:46

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '102.0' F	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Form: Symptom Log (13)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	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)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Form: Symptom Log (13)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:39

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Richard Novak (b) (4)	04 Oct 2020 20:46:46
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

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[Date](#)

Audit	User	Time (GMT)
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) (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)	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)	07 Oct 2020 22:48:50

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '0'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '95'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	07 Oct 2020 22:48:50

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered '101.0' F	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:39

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:02
User entered 'None (None)'	Andrea Wendrow (b) (4)	07 Oct 2020 22:48:50

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Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:39

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:15
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	26 Sep 2020 18:30:56

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:39

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	26 Sep 2020 18:30:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:39

[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

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[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:15
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	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

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[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:15
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 18:30:56
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:15
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 18:30:56
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:15
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 18:30:56
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:15
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 18:30:56
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 18:30:56

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

Did the subject have Respiratory Rates $\geq$ 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

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[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:25
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 19:22:30
	(b) (4)	

US3492117

Folder: Covid-19 Assessment 22 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:29:39

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	19 Oct 2020 22:04:33
	(b) (4)	

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:29:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered '25 Sep 2020'	Andrea Wendrow (b) (4)	19 Oct 2020 22:04:33
	(b) (4)	

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	19 Oct 2020 22:04:33
	(b) (4)	

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:29:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:29:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	19 Oct 2020 22:04:33
	(b) (4)	

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:29:39

[Date of Collection](#)

Audit	User	Time (GMT)
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) (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)	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)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	19 Oct 2020 22:04:33
	(b) (4)	

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:29:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered '1 Oct 2020'	Andrea Wendrow (b) (4)	19 Oct 2020 22:04:33
	(b) (4)	

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Diana Bahena (b) (4)	20 Oct 2020 21:21:45
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:29:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	20 Oct 2020 21:21:45
User entered empty.	Andrea Wendrow (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:29:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Andrea Wendrow (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:29:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Diana Bahena (b) (4)	20 Oct 2020 21:21:45
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:29:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	20 Oct 2020 21:21:45
User entered empty.	Andrea Wendrow (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:29:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Andrea Wendrow (b) (4)	19 Oct 2020 22:04:33
	(b) (4)	

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:29:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:29:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	20 Oct 2020 21:21:45
User entered empty.	Andrea Wendrow (b) (4)	19 Oct 2020 22:04:33

US3492117

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:47
User entered '23 Sep 2020'	Andrea Wendrow (b) (4)	26 Sep 2020 18:52:10
	(b) (4)	

US3492117

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:47
User entered 'Home (Home)'	Andrea Wendrow (b) (4)	26 Sep 2020 18:52:10

US3492117

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	26 Sep 2020 18:52:10

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	26 Sep 2020 18:57:52
	(b) (4)	

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered '23 Sep 2020'	Andrea Wendrow (b) (4)	26 Sep 2020 18:57:52
	(b) (4)	

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered '12:20'	Andrea Wendrow (b) (4)	26 Sep 2020 18:57:52
	(b) (4)	

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered '100.7' F	Andrea Wendrow (b) (4)	26 Sep 2020 18:57:52
	(b) (4)	

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered 'Oral (Oral)'	Andrea Wendrow (b) (4)	26 Sep 2020 18:57:52
	(b) (4)	

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered empty.	Andrea Wendrow (b) (4)	26 Sep 2020 18:57:52
	(b) (4)	

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered '82'	Andrea Wendrow (b) (4)	26 Sep 2020 18:57:52
	(b) (4)	

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered '14'	Andrea Wendrow (b) (4)	26 Sep 2020 18:57:52
	(b) (4)	

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered '144'	Andrea Wendrow (b) (4)	26 Sep 2020 18:57:52
	(b) (4)	

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:36:57
User entered '91'	Andrea Wendrow (b) (4)	26 Sep 2020 18:57:52
	(b) (4)	

US3492117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Sep 2020 18:57:52

US3492117

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:01
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	26 Sep 2020 18:58:11

US3492117

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:01
User entered '23 Sep 2020'	Andrea Wendrow (b) (4)	26 Sep 2020 18:58:11
	(b) (4)	

US3492117

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:29:39

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:05
User entered '23 Sep 2020'	Andrea Wendrow (b) (4)	26 Sep 2020 19:10:45

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:10
User entered 'Yes (Y)'	Diana Bahena (b) (4)	20 Oct 2020 21:10:53
	(b) (4)	

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:10
User entered '20 Oct 2020'	Diana Bahena (b) (4)	20 Oct 2020 21:10:53
	(b) (4)	

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:10
User entered 'Clinic (Clinic)'	Diana Bahena (b) (4)	20 Oct 2020 21:10:53
	(b) (4)	

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	20 Oct 2020 21:10:53

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered 'Yes (Y)'	Diana Bahena (b) (4)	20 Oct 2020 21:12:09
	(b) (4)	

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered '20 Oct 2020'	Diana Bahena (b) (4)	20 Oct 2020 21:12:09
	(b) (4)	

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered '15:50'	Diana Bahena (b) (4)	20 Oct 2020 21:12:09
	(b) (4)	

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered '99' F	Diana Bahena (b) (4)	20 Oct 2020 21:12:09
	(b) (4)	

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered 'Other (Other)'	Diana Bahena (b) (4)	20 Oct 2020 21:12:09
	(b) (4)	

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered 'tympanic'	Diana Bahena (b) (4)	20 Oct 2020 21:12:09
	(b) (4)	

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered '73'	Diana Bahena (b) (4)	20 Oct 2020 21:12:09
	(b) (4)	

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered '16'	Diana Bahena (b) (4)	20 Oct 2020 21:12:09
	(b) (4)	

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered '142'	Diana Bahena (b) (4)	20 Oct 2020 21:12:09
	(b) (4)	

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:13
User entered '80'	Diana Bahena (b) (4)	20 Oct 2020 21:12:09
	(b) (4)	

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Oct 2020 21:12:09

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:24
User entered 'Yes (Y)'	Diana Bahena (b) (4)	20 Oct 2020 21:12:19

US3492117

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:39

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:24
User entered '20 Oct 2020'	Diana Bahena (b) (4)	20 Oct 2020 21:12:19
	(b) (4)	

US3492117

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:29:39

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:28
User entered '20 Oct 2020'	Diana Bahena (b) (4)	20 Oct 2020 21:12:33
	(b) (4)	

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:29:39

[Visit Date](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 15:01:12
User closed query 'Per CDM: Please consider removing all data from this visit permitting inactivation of forms as it appears to be a duplicate of Illness Visit Day 1' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:01:10
Query 'Data is required. Please complete.' answered with 'asked to remove' (Site from System).	Andrea Wendrow (b) (4)	11 Nov 2020 03:47:35
Query 'Per CDM: Please consider removing all data from this visit permitting inactivation of forms as it appears to be a duplicate of Illness Visit Day 1' answered with 'done' (Site from DM).	Andrea Wendrow (b) (4)	11 Nov 2020 03:47:23
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 03:47:17
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:47:17
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:47:17
User opened query 'Per CDM: Please consider removing all data from this visit permitting inactivation of forms as it appears to be a duplicate of Illness Visit Day 1' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:40:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:49
User entered '23 Sep 2020'	Andrea Wendrow (b) (4)	03 Oct 2020 20:06:31

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:29:39

[Physical Exam](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:47:17
User entered '0' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:47:17
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:49
User entered '1'	Andrea Wendrow (b) (4)	03 Oct 2020 20:06:31

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:29:39

[Vital Signs](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:47:17
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:47:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:49
User entered '1'	Andrea Wendrow (b) (4)	03 Oct 2020 20:06:31
	(b) (4)	

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:29:39

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:47:17
User entered '0' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:47:17
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:49
User entered '1'	Andrea Wendrow (b) (4)	03 Oct 2020 20:06:31

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:29:39

[Pregnancy Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:49
User entered '0'	Andrea Wendrow (b) (4)	03 Oct 2020 20:06:31
	(b) (4)	

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 15:01:23
Query 'Data is required. Please complete.' answered with 'per query resolution' (Site from System).	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:59
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	11 Nov 2020 03:48:38
	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
User entered empty; reason for change Per Query Resolution	(b) (4)	
DataPoint Verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 19:37:55
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	03 Oct 2020 20:07:29
	(b) (4)	

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:55
User entered '23 Sep 2020'	Andrea Wendrow (b) (4)	03 Oct 2020 20:07:29

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:55
User entered '12:20'	Andrea Wendrow (b) (4)	03 Oct 2020 20:07:29

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 03:48:38
User entered '23 Sep 2020 12:20'	System	03 Oct 2020 20:07:29

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:55
User entered '100.7' F	Andrea Wendrow (b) (4)	03 Oct 2020 20:07:29
	(b) (4)	

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:55
User entered 'Oral (Oral)'	Andrea Wendrow (b) (4)	03 Oct 2020 20:07:29
	(b) (4)	

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:55
User entered empty.	Andrea Wendrow (b) (4)	03 Oct 2020 20:07:29
	(b) (4)	

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:55
User entered '82'	Andrea Wendrow (b) (4)	03 Oct 2020 20:07:29
	(b) (4)	

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 03:48:38
User entered 'bpm'	System	03 Oct 2020 20:07:29

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:55
User entered '14'	Andrea Wendrow (b) (4)	03 Oct 2020 20:07:29
	(b) (4)	

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 03:48:38
User entered 'breaths/min'	System	03 Oct 2020 20:07:29

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:55
User entered '144'	Andrea Wendrow (b) (4)	03 Oct 2020 20:07:29

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 03:48:38
User entered 'mmHg'	System	03 Oct 2020 20:07:29

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:37:55
User entered '91'	Andrea Wendrow (b) (4)	03 Oct 2020 20:07:29

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 03:48:38
User entered 'mmHg'	System	03 Oct 2020 20:07:29

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 15:01:27
Query 'Data is required. Please complete.' answered with 'per query resolution' (Site from System).	Andrea Wendrow (b) (4)	11 Nov 2020 03:49:38
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	11 Nov 2020 03:49:24
	Andrea Wendrow (b) (4)	11 Nov 2020 03:49:24
User entered empty; reason for change Per Query Resolution	(b) (4)	
DataPoint Verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:49:24
	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 19:38:06
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	03 Oct 2020 20:07:43
	(b) (4)	

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:49:24
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:49:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:06
User entered '23 Sep 2020'	Andrea Wendrow (b) (4)	03 Oct 2020 20:07:43
	(b) (4)	

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 15:01:30
Query 'Data is required. Please complete.' answered with 'per query resolution' (Site from System).	Andrea Wendrow (b) (4)	11 Nov 2020 03:50:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	11 Nov 2020 03:50:10
	Andrea Wendrow (b) (4)	11 Nov 2020 03:50:10
User entered empty; reason for change Per Query Resolution	(b) (4)	
	Andrea Wendrow (b) (4)	11 Nov 2020 03:50:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 19:38:11
User entered 'Yes (Y)'	(b) (4)	
	Andrea Wendrow (b) (4)	03 Oct 2020 20:08:03
	(b) (4)	

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:50:10
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:50:10
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:11
User entered '23 Sep 2020'	Andrea Wendrow (b) (4)	03 Oct 2020 20:08:03

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:50:10
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:50:10
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:11
User entered '12:40'	Andrea Wendrow (b) (4)	03 Oct 2020 20:08:03

US3492117

Folder: Unscheduled 23 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 03:50:10
User entered '23 Sep 2020 12:40'	System	03 Oct 2020 20:08:03

US3492117

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:29:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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 'USA-US101-2020-mRNA-1273-P301000001'	System	28 Sep 2020 14:31:28
User entered 'New'	(b) (4), (b) (6)	28 Sep 2020 14:31:28

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered '0'	Richard Novak (b) (4)	26 Sep 2020 19:08:07
	(b) (4)	

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered '0'	Richard Novak (b) (4)	26 Sep 2020 19:08:07
	(b) (4)	

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered '0'	Richard Novak (b) (4)	26 Sep 2020 19:08:07
	(b) (4)	

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered '0'	Richard Novak (b) (4)	26 Sep 2020 19:08:07
	(b) (4)	

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	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)	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

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

[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

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered '0'	Richard Novak (b) (4)	26 Sep 2020 19:08:07
	(b) (4)	

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:47
User entered '1'	Richard Novak (b) (4) (b) (4)	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Narrative](#)

Audit	User	Time (GMT)
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) (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)	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)	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
User closed query 'PV Query: Please clarify symptom reported as "choriza". ' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 23:53:18

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please clarify symptom reported as "choriza". ' answered with 'choriza is the medical term for common cold, usually spelled coryza' (Site from Safety).	Andrea Wendrow (b) (4)	(b) (4) 01 Nov 2020 21:15:25
Query 'PV Query: Please fill out the COVID-19 assessment page for 22, 24 and 25 Sep 2020. '	Andrea Wendrow (b) (4)	(b) (4) 01 Nov 2020 21:15:20
answered with 'please clarify' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 19:03:43
User opened query 'PV Query: Please clarify symptom reported as "choriza".		
' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 19:03:25
User opened query 'PV Query: Please fill out the COVID-19 assessment page for 22, 24 and 25 Sep 2020. '		
(Site from Safety).		

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

[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, chori- 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 relief 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

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	26 Sep 2020 19:08:07

US3492117

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 19:08:07

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:29:39

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Elena Llinas (b) (4)	24 Sep 2020 22:04:38
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:33:05

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (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) (b) (4)	09 Nov 2020 16:37:34
Data point term sent to Coder Coding entries removed.	System Diana Bahena (b) (4) (b) (4)	09 Nov 2020 16:37:09 09 Nov 2020 16:36:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	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) (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) (b) (4)	24 Sep 2020 22:08:42
Data point term sent to Coder User entered 'Tylenol'	System Elena Llinas (b) (4) (b) (4)	24 Sep 2020 22:07:48 24 Sep 2020 22:06:55

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Diana Bahena (b) (4)	09 Nov 2020 16:36:32
	(b) (4)	
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) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Fever and headache'	Elena Llinas (b) (4)	24 Sep 2020 22:06:55
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '1000'	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: 26 Nov 2020 09:29:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
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) (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

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'once (ONCE)'	Richard Novak (b) (4)	02 Oct 2020 21:21:15
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Oral (ORAL)'	Richard Novak (b) (4)	02 Oct 2020 21:21:15
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened 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). User entered 'Yes (Y)'	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	30 Oct 2020 13:11:05 02 Oct 2020 21:21:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 02:12:56
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). User entered 'Yes (Y)' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	06 Nov 2020 17:49:12
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). User entered 'No (N)'	(b) (4), (b) (6) Diana Bahena (b) (4) (b) (4)	06 Nov 2020 10:23:15 20 Oct 2020 21:24:06

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Supplement'	Diana Bahena (b) (4)	20 Oct 2020 21:24:06
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '2000'	Diana Bahena (b) (4)	20 Oct 2020 21:24:06
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4)	20 Oct 2020 21:24:06
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'once daily (QD)' reason for change:	(b) (4)	
Data Entry Error	Diana Bahena (b) (4)	20 Oct 2020 21:24:37
User entered 'other (OTHER)'	(b) (4)	
	Diana Bahena (b) (4)	20 Oct 2020 21:24:06
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Oral (ORAL)'	Diana Bahena (b) (4)	20 Oct 2020 21:24:06
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4)	20 Oct 2020 21:24:06
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'un UNK 2015'	Diana Bahena (b) (4)	20 Oct 2020 21:24:06
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '0'	Diana Bahena (b) (4)	20 Oct 2020 21:24:06
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Yes (Y)'	Diana Bahena (b) (4)	20 Oct 2020 21:24:06
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4)	20 Oct 2020 21:24:06
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'No (N)'	Diana Bahena (b) (4)	20 Oct 2020 21:24:06
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	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)	20 Oct 2020 21:25:15
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 02:13:02
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). User entered 'Yes (Y)' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	06 Nov 2020 17:48:16
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). User entered 'No (N)'	(b) (4), (b) (6) Diana Bahena (b) (4) (b) (4)	06 Nov 2020 17:48:05 06 Nov 2020 10:23:35 20 Oct 2020 21:25:15

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Supplement'	Diana Bahena (b) (4)	20 Oct 2020 21:25:15
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '50'	Diana Bahena (b) (4)	20 Oct 2020 21:25:15
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4)	20 Oct 2020 21:25:15
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'once daily (QD)'	Diana Bahena (b) (4)	20 Oct 2020 21:25:15
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4)	20 Oct 2020 21:25:15
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Oral (ORAL)'	Diana Bahena (b) (4)	20 Oct 2020 21:25:15
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4)	20 Oct 2020 21:25:15
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'un UNK 2015'	Diana Bahena (b) (4)	20 Oct 2020 21:25:15
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '0'	Diana Bahena (b) (4)	20 Oct 2020 21:25:15
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Yes (Y)'	Diana Bahena (b) (4)	20 Oct 2020 21:25:15
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4)	20 Oct 2020 21:25:15
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'No (N)'	Diana Bahena (b) (4)	20 Oct 2020 21:25:15
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 02:13:09
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). User entered 'No (N)'	(b) (4), (b) (6) Diana Bahena (b) (4) (b) (4)	06 Nov 2020 10:24:02 20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Supplement'	Diana Bahena (b) (4)	20 Oct 2020 21:27:52
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '1'	Diana Bahena (b) (4)	20 Oct 2020 21:27:52
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4)	20 Oct 2020 21:27:52
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'once daily (QD)'	Diana Bahena (b) (4)	20 Oct 2020 21:27:52
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4)	20 Oct 2020 21:27:52
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Oral (ORAL)'	Diana Bahena (b) (4)	20 Oct 2020 21:27:52

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4)	20 Oct 2020 21:27:52
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'un UNK 2015'	Diana Bahena (b) (4)	20 Oct 2020 21:27:52
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered '0'	Diana Bahena (b) (4)	20 Oct 2020 21:27:52
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'Yes (Y)'	Diana Bahena (b) (4)	20 Oct 2020 21:27:52
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered empty.	Diana Bahena (b) (4)	20 Oct 2020 21:27:52
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:59
User entered 'No (N)'	Diana Bahena (b) (4)	20 Oct 2020 21:27:52
	(b) (4)	

US3492117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[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: 26 Nov 2020 09:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (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) (b) (4)	11 Nov 2020 21:50:37
Data point term sent to Coder	System	09 Nov 2020 17:15:12
User entered 'Ibuprofen'	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: 26 Nov 2020 09:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:39

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '800'	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: 26 Nov 2020 09:29:39

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	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: 26 Nov 2020 09:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:29:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:39

[Indication](#)

Audit	User	Time (GMT)
User entered 'Myalgias'	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: 26 Nov 2020 09:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5/325'	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: 26 Nov 2020 09:29:39

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:39

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	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: 26 Nov 2020 09:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:39

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered '22 Sep 2020'	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: 26 Nov 2020 09:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	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: 26 Nov 2020 09:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 17:17:13

US3492117

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:29:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:39:06
User entered 'No (N)'	Nusirat Williams (b) (4)	10 Sep 2020 19:33:10

US3492117

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:29:39

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	Andrea Wendrow (b) (4)	29 Oct 2020 23:11:56
	(b) (4)	

US3492117

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:29:39

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

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

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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

Generated On: 26 Nov 2020 09:29:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 23:55:23
User entered '1'	(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: 26 Nov 2020 09:29:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:29:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:38:23
User entered '1'	(b) (4), (b) (6)	02 Nov 2020 23:55:35