

US3402194 (Prod: Meridian Clinical Research, LLC)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:24:34

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US3402194

Form: Participant Creation

Generated On: 26 Nov 2020 09:24:34

[Participant ID](#)

US3402194

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

US3402194

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	02 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3402194

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:34

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	57
Age Units	YEARS
Age (Derived)	58
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3402194

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:34

Date of Informed Consent (<i>dd MMM yyyy</i>)	2 AUG 2020
Month and Year of Informed Consent (derived)	AUG 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

US3402194

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:24:34

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3402194

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:24:34

Were any significant conditions reported?

Yes ☒

No ☐

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:34

Condition	TYPE 1 DIABETES
Start date (dd MMM yyyy)	UN UNK 1979
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 1979
Start Year (derived)	1979
Stop Month and Year (derived)	
Stop Year (derived)	

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:34

Condition	PERIPHERAL VASCULAR DISEASE
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:34

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN MAY 2017
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)	MAY 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	2 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:15 (24 HR)
Vital Signs Date and Time (derived)	2 AUG 2020 16:15
Height (<i>xxx.x</i>)	160 cm
Weight (<i>xxx.x</i>)	99.7 kg
BMI (<i>xxx.x</i>)	38.94531 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402194

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 AUG 2020

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

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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 NONE

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

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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

US3402194

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	2 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3402194

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:34

What was the date of randomization? (dd MMM yyyy) 02 AUG 2020

What was the participant's randomization number? 142630

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 ☒

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:34

Height	ND - Not Done
Weight	ND - Not Done

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

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)	2 AUG 2020
Time of assessment (00:00-23:59)	16:15 (24 HR)
Vital Signs Date and Time (derived)	2 AUG 2020 16:15
Temperature (xxx.x)	37.0 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	56 mmHg
Diastolic Blood Pressure units	MMHG

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

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)	2 AUG 2020
Time of assessment (00:00-23:59)	17:27 (24 HR)
Vital Signs Date and Time (derived)	2 AUG 2020 17:27
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3402194

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 AUG 2020

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

US3402194

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

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) 2 AUG 2020

What was the treatment time? (00:00-23:59) 16:48 (24 HR)

Treatment Date and Time (derived) 2 AUG 2020 16:48

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

US3402194

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:34

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	2 AUG 2020
Collection time (<i>00:00-23:59</i>)	16:25 (24 HR)
Collection date and time (derived)	2 AUG 2020 16:25

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:24:34

Collection date (dd MMM yyyy)			2 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:28	2 AUG 2020 16:28
Nasopharyngeal Swab 2	No		

US3402194

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

02 AUG 2020 17:27

PC Open Date & Time

02 AUG 2020 17:08

PC Close Date & Time

02 AUG 2020 19:38

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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	02 AUG 2020 22:45
PC Open Date & Time	02 AUG 2020 20:33
PC Close Date & Time	03 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 09:14

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 12:10

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 12:00

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:34

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 06 AUG 2020 12:00

PC Close Date & Time 07 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:34

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

98.1 °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

07 AUG 2020 12:12

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:34

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

08 AUG 2020 12:52

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

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

02 AUG 2020 17:28

PC Open Date & Time

02 AUG 2020 17:08

PC Close Date & Time

02 AUG 2020 19:38

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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

02 AUG 2020 22:46

PC Open Date & Time

02 AUG 2020 20:33

PC Close Date & Time

03 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

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

04 AUG 2020 09:15

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

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

04 AUG 2020 12:11

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

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

05 AUG 2020 12:00

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:34

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

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

07 AUG 2020 12:12

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

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

08 AUG 2020 12:52

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

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

No ☒

Yes ☐

PC Time stamp	02 AUG 2020 17:28
PC Open Date & Time	02 AUG 2020 17:08
PC Close Date & Time	02 AUG 2020 19:38

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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

No ☒

Yes ☐

PC Time stamp	02 AUG 2020 22:47
PC Open Date & Time	02 AUG 2020 20:33
PC Close Date & Time	03 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

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 ☒

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

Yes ☐	
PC Time stamp	04 AUG 2020 09:16
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

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 ☒

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

Yes ☐	
PC Time stamp	04 AUG 2020 12:11
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

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 ☒

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

Yes ☐	
PC Time stamp	05 AUG 2020 12:01
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

		Yes ☐
PC Time stamp		
PC Open Date & Time		06 AUG 2020 12:00
PC Close Date & Time		07 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

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 ☒

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

Yes ☐	
PC Time stamp	07 AUG 2020 12:13
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

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 ☒

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

Yes ☐	
PC Time stamp	08 AUG 2020 12:52
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3402194

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

Was Contact Attempted?

Yes ☒

No ☐

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

9 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402194

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402194

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402194

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402194

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

Was Contact Attempted?

Yes ☒

No ☐

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

23 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402194

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402194

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	2 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	15:07 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 15:07
Temperature (xxx.x)	37.1 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	16:32 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 16:32
Temperature (xxx.x)	37.0 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3402194

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

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)	2 SEP 2020
What was the treatment time? (00:00-23:59)	15:46 (24 HR)
Treatment Date and Time (derived)	2 SEP 2020 15:46
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3402194

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:34

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	2 SEP 2020
Collection time (<i>00:00-23:59</i>)	15:32 (24 HR)
Collection date and time (derived)	2 SEP 2020 15:32

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:24:34

Collection date (dd MMM yyyy)			2 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:36	2 SEP 2020 15:36
Nasopharyngeal Swab 2	No		

US3402194

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 16:31

PC Open Date & Time

02 SEP 2020 16:06

PC Close Date & Time

02 SEP 2020 18:36

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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 98.6 °F

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

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

PC Time Stamp	02 SEP 2020 19:37
PC Open Date & Time	02 SEP 2020 19:31
PC Close Date & Time	03 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:34

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 10:32

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 10:03

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 12:22

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 17:33

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:34

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 20:32

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:34

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.

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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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 12:02

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

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

02 SEP 2020 16:32

PC Open Date & Time

02 SEP 2020 16:06

PC Close Date & Time

02 SEP 2020 18:36

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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

02 SEP 2020 19:37

PC Open Date & Time

02 SEP 2020 19:31

PC Close Date & Time

03 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

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

04 SEP 2020 10:32

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

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

05 SEP 2020 10:03

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

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

05 SEP 2020 12:22

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:34

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

06 SEP 2020 17:33

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

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

07 SEP 2020 20:32

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

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

08 SEP 2020 12:02

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 16:32
PC Open Date & Time	02 SEP 2020 16:06
PC Close Date & Time	02 SEP 2020 18:36

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 19:38
PC Open Date & Time	02 SEP 2020 19:31
PC Close Date & Time	03 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

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 ☒

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

Yes ☐	
PC Time stamp	04 SEP 2020 10:32
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

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 ☒

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

Yes ☐	
PC Time stamp	05 SEP 2020 10:03
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

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 ☒

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

Yes ☐	
PC Time stamp	05 SEP 2020 13:13
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

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 ☒

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

Yes ☐	
PC Time stamp	06 SEP 2020 17:33
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

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 ☒

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

Yes ☐	
PC Time stamp	07 SEP 2020 20:33
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

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 ☒

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

Yes ☐	
PC Time stamp	08 SEP 2020 12:02
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3402194

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402194

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402194

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402194

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402194

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402194

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402194

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	30 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:11 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 14:11
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	84 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	61 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402194

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:34

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.

US3402194

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:34

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	30 SEP 2020
Collection time (<i>00:00-23:59</i>)	14:16 (24 HR)
Collection date and time (derived)	30 SEP 2020 14:16

US3402194

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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	02 OCT 2020 00:05:16
Patient Cloud Open Date & Time	02 OCT 2020 00:01
Patient Cloud Close Date & Time	06 OCT 2020 23:59

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

09 OCT 2020 00:02:01

Patient Cloud Open Date & Time

09 OCT 2020 00:01

Patient Cloud Close Date & Time

13 OCT 2020 23:59

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 OCT 2020 00:01:48

Patient Cloud Open Date & Time

16 OCT 2020 00:01

Patient Cloud Close Date & Time

20 OCT 2020 23:59

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 12:32:04

Patient Cloud Open Date & Time

30 OCT 2020 00:01

Patient Cloud Close Date & Time

03 NOV 2020 23:59

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 NOV 2020 00:02:13
Patient Cloud Open Date & Time	06 NOV 2020 00:01
Patient Cloud Close Date & Time	10 NOV 2020 23:59

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-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)	True
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	True
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐
Date and time of submission	13 NOV 2020 09:02:17
Patient Cloud Open Date & Time	13 NOV 2020 00:01
v6.020 DTW (1102)	118 of 2541

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

03 OCT 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

10 OCT 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

17 OCT 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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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20 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

31 OCT 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

14 NOV 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2020 00:01

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21 NOV 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

28 NOV 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

05 DEC 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

12 DEC 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

19 DEC 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

26 DEC 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

02 JAN 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

09 JAN 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

16 JAN 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

23 JAN 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

06 FEB 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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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13 FEB 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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20 FEB 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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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27 FEB 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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06 MAR 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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13 MAR 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

20 MAR 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

27 MAR 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

03 APR 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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10 APR 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

17 APR 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

24 APR 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

01 MAY 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

08 MAY 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

15 MAY 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

22 MAY 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

29 MAY 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

05 JUN 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

12 JUN 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

19 JUN 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

26 JUN 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

03 JUL 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

10 JUL 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

17 JUL 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

24 JUL 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

31 JUL 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

07 AUG 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

14 AUG 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

21 AUG 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

28 AUG 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

11 SEP 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

18 SEP 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

25 SEP 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

09 OCT 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

16 OCT 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

23 OCT 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

30 OCT 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

06 NOV 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

13 NOV 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

20 NOV 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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27 NOV 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

04 DEC 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

11 DEC 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

18 DEC 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

25 DEC 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

01 JAN 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

08 JAN 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

15 JAN 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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22 JAN 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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29 JAN 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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05 FEB 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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

Date and time of submission

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08 FEB 2022 00:01

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12 FEB 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

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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19 FEB 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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26 FEB 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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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22 MAR 2022 00:01

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26 MAR 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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 MAR 2022 00:01

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02 APR 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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 APR 2022 00:01

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09 APR 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

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

[Patient Cloud Open Date & Time](#)

12 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

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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19 APR 2022 00:01

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23 APR 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

30 APR 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

07 MAY 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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14 MAY 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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21 MAY 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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28 MAY 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

04 JUN 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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11 JUN 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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18 JUN 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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25 JUN 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

02 JUL 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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°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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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09 JUL 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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16 JUL 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

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23 JUL 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

30 JUL 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

06 AUG 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

13 AUG 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

20 AUG 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

27 AUG 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

03 SEP 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

10 SEP 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

17 SEP 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

24 SEP 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

01 OCT 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

[Patient Cloud Close Date & Time](#)

08 OCT 2022 23:59

US3402194

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402194

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402194

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

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

US3402194

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:24:34

Date of Contact	13 NOV 2020
Time of Contact	11:30
Date and Time of Contact (derived)	13 NOV 2020 11:30
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 ☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	99.0 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)	338 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	99.0 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)	342 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	83 %	
O2 Saturation Units	%	
Temperature	99.0 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)	346 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	98.9 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)	350 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	97.3 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)	354 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
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)	358 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	06 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)	362 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	07 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)	366 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	08 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)	370 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	09 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)	374 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)	378 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)	382 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)	386 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.3 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)	390 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
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)	394 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
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)	398 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
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)	402 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
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)	406 of 2541	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

	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	☐

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:24:34

Date of Visit	13 NOV 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	13 NOV 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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

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 _____ 16 NOV 2020

End Date _____

Oxygen Saturation _____ 83 %

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:

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

Ventilator Support:

High-Flow Oxygen? Yes ☒ No ☐

Start Date 16 OCT 2020

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:24:34

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:24:34

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	15 NOV 2020
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3402194

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	13 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	11:37 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 11:37
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	99.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	87 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402194

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 NOV 2020

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

US3402194

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:24:34

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 NOV 2020

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

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)	

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:34

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.

US3402194

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:24:34

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3402194

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:24:34

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

AEID	USA-US059-2020-MRNA-1273-P30 1000018
Adverse event	COVID-19
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☒ No ☐
Start date (dd MMM yyyy)	05 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
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	True
Hospital Admission Date (dd MMM yyyy)	16 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	424 of 2541

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

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	SUBJECT ADMITTED 16NOV2020 NO RECORDS AVAILABLE YET.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:24:34

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

Yes ☒

No ☐

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

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	ADMELOG U-100
Prophylaxis	Yes ☐ No ☒
Indication	TYPE 1 DIABETES
Dose per administration	100
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNITS
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 ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

	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 1979
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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	BRILINTA
Prophylaxis	Yes ☐ No ☒
Indication	PERIPHERAL VASCULAR DISEASE
Dose per administration	90
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 ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

	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)	UN	UNK 2018
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	☒

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	CORONARY ARTERY DISEASE
Dose per administration	20
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 ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

	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 MAY 2017	
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	☒

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	LISINOPRIL
Prophylaxis	Yes ☐ No ☒
Indication	CORONARY ARTERY DISEASE
Dose per administration	2.5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

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 MAY 2017
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 ☒

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	ALBUTEROL
Prophylaxis	Yes ☐ No ☒
Indication	SARS-COV-2
Dose per administration	90
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 ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

	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)	16 NOV 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	☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	DEXAMETHASONE
Prophylaxis	Yes ☐ No ☒
Indication	SARS-COV-2
Dose per administration	6
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 ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

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)	16 NOV 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☐ No ☒
Indication	SARS-COV-2
Dose per administration	650
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	EVERY 4 HOURS Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

	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)		16 NOV 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	☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	DEXTROSE
Prophylaxis	Yes ☐ No ☒
Indication	SARS-COV-2
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 ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

	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)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		16 NOV 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	☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	FUROSEMIDE
Prophylaxis	Yes ☐ No ☒
Indication	SARS-COV-2
Dose per administration	20
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 ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

	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)		16 NOV 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	ASCORBIC ACID
Prophylaxis	Yes ☐ No ☒
Indication	SARS-COV-2
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	EVERY 8 HOURS Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

	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)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		17 NOV 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	☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	ASPIRIN
Prophylaxis	Yes ☒ No ☐
Indication	SARS-COV-2
Dose per administration	81
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 ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

	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)		16 NOV 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	GLUCOSE CHEWABLE TABLET
Prophylaxis	Yes ☐ No ☒
Indication	SARS-COV-2
Dose per administration	12
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 ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

	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)	16 NOV 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	☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	HEPARIN
Prophylaxis	Yes ☐ No ☒
Indication	SARS-COV-2
Dose per administration	40
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNITS/KG
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	EVERY 6 HOURS
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

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)	16 NOV 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 ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	D5W
Prophylaxis	Yes ☐ No ☒
Indication	SARS-COV-2
Dose per administration	0-24
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNITS/KG/HOUR
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	EVERY 6 HOURS
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

	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)		16 NOV 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	☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	INSULIN GLARGINE
Prophylaxis	Yes ☐ No ☒
Indication	DIABETES TYPE 1
Dose per administration	30
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNITS
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 ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

	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)	16 NOV 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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	INSULIN LISPRO
Prophylaxis	Yes ☐ No ☒
Indication	DIABETES TYPE 1
Dose per administration	2-6
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNITS
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 ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

	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)		16 NOV 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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	REMDESIVIR
Prophylaxis	Yes ☐ No ☒
Indication	SARS-COV-2
Dose per administration	100
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

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)	18 NOV 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	SODIUM CHLORIDE INFUSION
Prophylaxis	Yes ☐ No ☒
Indication	SARS-COV-2
Dose per administration	0.9
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 ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

	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)		16 NOV 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	☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	THIAMINE
Prophylaxis	Yes ☐ No ☒
Indication	SARS-COV-2
Dose per administration	100
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	EVERY 8 HOURS Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

	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)		17 NOV 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	☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	
Prophylaxis	Yes ☐
	No ☐
Indication	
Dose per administration	
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 ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:34

	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) _____		
Start date completely unknown _____		
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	☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

Name of Medication	OXYGEN
Prophylaxis	Yes ☐ No ☒
Indication	SARS COVID 19
Dose per administration	6
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	LITERS
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	CONTINUOUS
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

	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)	16 NOV 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	☐

US3402194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:24:34

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3402194

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:24:34

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3402194

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:24:34

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 ☐

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

SAEID	USA-US059-2020-MRNA-1273-P301000018
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:24:34

SAEID	USA-US059-2020-MRNA-1273-P301000018
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	18/NOV/2020 15:54
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

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:24:34

SAEID	USA-US059-2020-MRNA-1273-P301000018
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/NOV/2020 15:03
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

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:24:34

SAEID	USA-US059-2020-MRNA-1273-P301000018
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	24/NOV/2020 15:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3402194 (Prod: Meridian Clinical Research, LLC)

US3402194

Form: Participant Creation

Generated On: 26 Nov 2020 09:24:34

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3402194'	RWS_ENDPOINT ENDPOINT (b) (4) 	02 Aug 2020 20:19:12

US3402194

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:14

US3402194

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '02 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	02 Aug 2020 20:19:13

US3402194

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:14

US3402194

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	03 Aug 2020 14:32:14

US3402194

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:34

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1962'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Aug 2020 20:19:14

US3402194

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:34

[Age](#)

Audit	User	Time (GMT)
User entered '57'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:34

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:34

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '58'	System	02 Aug 2020 20:57:07

US3402194

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:34

Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:34

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:34

White

Audit	User	Time (GMT)
User entered '1'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:34

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:34

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:34

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:34

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:34

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:34

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:34

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:34

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '2 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	02 Aug 2020 20:57:07

US3402194

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	02 Aug 2020 20:57:07

US3402194

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '2020'	System	02 Aug 2020 20:57:07

US3402194

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:34

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Tarin Gordon (b) (4) (b) (4)	02 Aug 2020 20:57:07

US3402194

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	02 Aug 2020 20:57:07

US3402194

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	02 Aug 2020 20:57:07

US3402194

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:34

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	02 Aug 2020 20:57:07

US3402194

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:34

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	02 Aug 2020 20:57:07

US3402194

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:34

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Aug 2020 20:19:13

US3402194

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:34

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Aug 2020 20:57:11

US3402194

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	02 Aug 2020 20:57:11

US3402194

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:24:34

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:29

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:34

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 1 diabetes mellitus, LLT: Type 1 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 17:57:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 17:57:04
Data point term sent to Coder	System	03 Aug 2020 14:34:18
User entered 'type 1 diabetes'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'un UNK 1979'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Jan 1979'	System	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '1979'	System	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:34

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLG: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Peripheral vascular disorder, LLT: Peripheral vascular disease - version MedDRA\23.0.	Coder Import (b) (4)	03 Aug 2020 14:35:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Aug 2020 14:35:06
Data point term sent to Coder	System	03 Aug 2020 14:34:18
User entered 'peripheral vascular disease'	Traci Hull (b) (4)	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '2018'	System	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:34

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 14:36:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 14:36:00
Data point term sent to Coder	System	03 Aug 2020 14:35:18
User entered 'coronary artery disease'	Traci Hull (b) (4)	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'un May 2017'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'May 2017'	System	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '2017'	System	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '16:15'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '2 Aug 2020 16:15'	System	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '160' cm	Traci Hull (b) (4)	03 Aug 2020 14:37:39
DataPoint set to visible.	(b) (4) System	02 Aug 2020 20:57:11

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '99.7' kg	Traci Hull (b) (4)	03 Aug 2020 14:37:39
DataPoint set to visible.	(b) (4) System	02 Aug 2020 20:57:11

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '38.94531'	System	16 Sep 2020 23:40:49
User entered '38.9'	System	03 Aug 2020 14:37:39
DataPoint set to visible.	System	02 Aug 2020 20:57:11

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	03 Aug 2020 14:37:39
DataPoint set to visible.	System	02 Aug 2020 20:57:11

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: For Screening and Visit 1 on the same day, to avoid duplication of data, TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP should be recorded as 'ND-NOT DONE'. Please remove the data and enter 'ND - NOT DONE' in the data field of EDC. Thank you	(b) (4), (b) (6)	12 Oct 2020 09:45:01
' (Site from DM). Query 'Per CDM re-query: For Screening and Visit 1 on the same day, to avoid duplication of data, TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP should be recorded as 'ND-NOT DONE'. Please remove the data and enter 'ND - NOT DONE' in the data field of EDC. Thank you	Tammy Kohn (b) (4) (b) (4)	09 Oct 2020 14:48:47
' answered with 'NOT DONE' (Site from DM). User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	09 Oct 2020 14:48:41
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:16:56
User opened query 'Per CDM re-query: For Screening and Visit 1 on the same day, to avoid duplication of data, TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP should be recorded as 'ND-NOT DONE'. Please remove the data and enter 'ND - NOT DONE' in the data field of EDC. Thank you	(b) (4), (b) (6)	09 Oct 2020 12:16:48
' (Site from DM). Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update data fields accordingly.' answered with 'CORRECT AS IS' (Site from DM).	Traci Hull (b) (4) (b) (4)	08 Oct 2020 14:35:53
v6.020 DTW (1102)		547 of 2541

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update data fields accordingly.' (Site from DM). User entered '37.0' C	(b) (4), (b) (6)	23 Sep 2020 17:49:05
	Traci Hull (b) (4)	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	09 Oct 2020 14:48:41
User entered 'Oral (Oral)'	Traci Hull (b) (4)	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	09 Oct 2020 14:48:41
User entered '78'	Traci Hull (b) (4)	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	09 Oct 2020 14:48:41
User entered '14'	Traci Hull (b) (4)	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	09 Oct 2020 14:48:41
User entered '104'	Traci Hull (b) (4)	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	09 Oct 2020 14:48:41
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	23 Sep 2020 17:49:38
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CORRECT AS IS. NOT CLINICALLY SIGNIFICANT' (Site from System).	Traci Hull (b) (4)	22 Sep 2020 20:03:12
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:40:49
User entered '56'	Traci Hull (b) (4)	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:38:01

US3402194

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	06 Sep 2020 12:33:30
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		03 Sep 2020 12:27:49
User entered '2 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:38:01

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

[Specify](#)

Audit	User	Time (GMT)
User entered 'none'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '1'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:34

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:38:17

US3402194

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '2 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:38:17

US3402194

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:38:17

US3402194

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	03 Aug 2020 14:38:17

US3402194

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '02 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	02 Aug 2020 20:19:18

US3402194

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:34

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:41:18
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:41:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Aug 2020 20:19:18
User entered '142630' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Aug 2020 20:19:18

US3402194

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Aug 2020 20:19:18

US3402194

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:34

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)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:38:31

US3402194

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:38:31

US3402194

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:38:31

US3402194

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:34

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:38:31

US3402194

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:34

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:38:31

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:34

Height

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:21:35
Query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' answered with 'DATA UPDATED NOT DONE ND' (Site from DM).	Tammy Kohn (b) (4)	13 Oct 2020 18:26:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Oct 2020 18:26:40
User opened query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:39:32
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)	12 Oct 2020 14:39:32
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'CORRECT AS IS' (Site from DM).	Traci Hull (b) (4)	08 Oct 2020 14:35:34
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)	23 Sep 2020 17:49:24
User entered '160' cm	Traci Hull (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:34

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	13 Oct 2020 18:26:40
User entered '99.7' kg	Traci Hull (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:34

Height

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:21:35
Query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' answered with 'DATA UPDATED NOT DONE ND' (Site from DM).	Tammy Kohn (b) (4)	13 Oct 2020 18:26:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Oct 2020 18:26:40
User opened query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:39:32
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)	12 Oct 2020 14:39:32
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'CORRECT AS IS' (Site from DM).	Traci Hull (b) (4)	08 Oct 2020 14:35:34
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)	23 Sep 2020 17:49:24
User entered '160' cm	Traci Hull (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:34

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	13 Oct 2020 18:26:40
User entered '99.7' kg	Traci Hull (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '16:15'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '2 Aug 2020 16:15'	System	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.0' C	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '78'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '14'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '104'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per previous query, please confirm if this result should be considered Clinically Significant or not.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 17:49:14
Query 'Per CDM: Per previous query, please confirm if this result should be considered Clinically Significant or not.' answered with 'CORRECT AS IS. NOT CLINICALLY SIGNIFICANT' (Site from DM).	Traci Hull (b) (4) (b) (4)	22 Sep 2020 20:02:15
User opened query 'Per CDM: Per previous query, please confirm if this result should be considered Clinically Significant or not.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 14:53:52
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 14:53:08
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'correct as is' (Site from System).	Traci Hull (b) (4) (b) (4)	18 Sep 2020 12:34:09
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:40:49
User entered '56'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:34

Height

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:21:35
Query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' answered with 'DATA UPDATED NOT DONE ND' (Site from DM).	Tammy Kohn (b) (4)	13 Oct 2020 18:26:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Oct 2020 18:26:40
User opened query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:39:32
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)	12 Oct 2020 14:39:32
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'CORRECT AS IS' (Site from DM).	Traci Hull (b) (4)	08 Oct 2020 14:35:34
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)	23 Sep 2020 17:49:24
User entered '160' cm	Traci Hull (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:34

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	13 Oct 2020 18:26:40
User entered '99.7' kg	Traci Hull (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 14:02:50
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 minutes' (Site from System).	Traci Hull (b) (4)	03 Aug 2020 14:40:29
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	03 Aug 2020 14:40:19
User entered '17:27'	Traci Hull (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '2 Aug 2020 17:27'	System	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '12'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '120'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '65'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:40

US3402194

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:34

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:40

US3402194

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	02 Aug 2020 20:57:32

US3402194

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	02 Aug 2020 20:57:32

US3402194

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	02 Aug 2020 20:57:32

US3402194

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	02 Aug 2020 20:57:32

US3402194

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '2 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	02 Aug 2020 20:57:32

US3402194

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '16:48'	Tarin Gordon (b) (4) (b) (4)	02 Aug 2020 20:57:32

US3402194

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '2 Aug 2020 16:48'	System	02 Aug 2020 20:57:32

US3402194

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Tarin Gordon (b) (4) (b) (4)	02 Aug 2020 20:57:32

US3402194

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	02 Aug 2020 20:57:32

US3402194

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	02 Aug 2020 20:57:32

US3402194

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:01

US3402194

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under Visit 1 Day 1 Visit with date 03AUG2020 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 06:30:18
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under Visit 1 Day 1 Visit with date 03AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'DATA WAS UPDATED BY THE LAB.' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	26 Oct 2020 12:17:21
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under Visit 1 Day 1 Visit with date 03AUG2020 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)	23 Oct 2020 12:02:03
User entered '2 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:01

US3402194

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '16:25'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:01

US3402194

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '2 Aug 2020 16:25'	System	03 Aug 2020 14:41:01

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:24:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:24:34

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:24:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:24:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '16:28'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: The collection date of Visit 2 Day 29 in EDC is entered as 02AUG2020. However, collection date in GCL for the same visit is recorded as 03AUG2020. Please review and confirm the correct collection date. Thank you' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:15:18
User entered '2 Aug 2020 16:28'	System	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:34

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:55

US3402194

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 14:41:55

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:27:11', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c579a454-de27-44d5-8028-e54a57943564'	System	02 Aug 2020 21:27:40
User entered 'Yes (Y)'	System	02 Aug 2020 21:27:40

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:27:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c579a454-de27-44d5-8028-e54a57943564'	System	02 Aug 2020 21:27:40
User entered '98.1'	System	02 Aug 2020 21:27:40

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:27:23', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c579a454-de27-44d5-8028-e54a57943564'	System	02 Aug 2020 21:27:40
User entered 'No (N)'	System	02 Aug 2020 21:27:40

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:27:30', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c579a454-de27-44d5-8028-e54a57943564'	System	02 Aug 2020 21:27:40
User entered '02 Aug 2020 17:27'	System	02 Aug 2020 21:27:40

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 17:08'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 19:38'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:44:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'f3dbd53a-f194-4c7d-a0a4-cebd5185b2e9'	System	03 Aug 2020 02:45:35
User entered 'Yes (Y)'	System	03 Aug 2020 02:45:35

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:45:05', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'f3dbd53a-f194-4c7d-a0a4-cebd5185b2e9'	System	03 Aug 2020 02:45:35
User entered '98.1'	System	03 Aug 2020 02:45:35

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:45:23', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'f3dbd53a-f194-4c7d-a0a4-cebd5185b2e9'	System	03 Aug 2020 02:45:35
User entered 'No (N)'	System	03 Aug 2020 02:45:35

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:45:33', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'f3dbd53a-f194-4c7d-a0a4-cebd5185b2e9'	System	03 Aug 2020 02:45:35
User entered '02 Aug 2020 22:45'	System	03 Aug 2020 02:45:35

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 20:33'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 2'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:14:27', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ca650b6f-1039-41af-8314-400f5163f0db'	System	04 Aug 2020 13:14:53
User entered 'Yes (Y)'	System	04 Aug 2020 13:14:53

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:14:38', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ca650b6f-1039-41af-8314-400f5163f0db' User entered '98.1'	System	04 Aug 2020 13:14:53
	System	04 Aug 2020 13:14:53

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:14:45', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ca650b6f-1039-41af-8314-400f5163f0db'	System	04 Aug 2020 13:14:53
User entered 'No (N)'	System	04 Aug 2020 13:14:53

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:14:50', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ca650b6f-1039-41af-8314-400f5163f0db'	System	04 Aug 2020 13:14:53
User entered '04 Aug 2020 09:14'	System	04 Aug 2020 13:14:53

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 3'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:10:21', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '99733174-b331-43bf-8cac-f18e3c8fcf03'	System	04 Aug 2020 16:10:42
User entered 'Yes (Y)'	System	04 Aug 2020 16:10:42

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:10:30', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '99733174-b331-43bf-8cac-f18e3c8fcf03'	System	04 Aug 2020 16:10:42
User entered '98.1'	System	04 Aug 2020 16:10:42

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:10:37', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '99733174-b331-43bf-8cac-f18e3c8fcf03'	System	04 Aug 2020 16:10:42
User entered 'No (N)'	System	04 Aug 2020 16:10:42

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:10:41', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '99733174-b331-43bf-8cac-f18e3c8fcf03'	System	04 Aug 2020 16:10:42
User entered '04 Aug 2020 12:10'	System	04 Aug 2020 16:10:42

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 4'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:15', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ef308d3c-5672-4ee5-b374-1f02b1b7dd3d'	System	05 Aug 2020 16:00:26
User entered 'Yes (Y)'	System	05 Aug 2020 16:00:26

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:20', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ef308d3c-5672-4ee5-b374-1f02b1b7dd3d' User entered '98.1'	System	05 Aug 2020 16:00:26
	System	05 Aug 2020 16:00:26

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:23', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ef308d3c-5672-4ee5-b374-1f02b1b7dd3d'	System	05 Aug 2020 16:00:26
User entered 'No (N)'	System	05 Aug 2020 16:00:26

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:25', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ef308d3c-5672-4ee5-b374-1f02b1b7dd3d'	System	05 Aug 2020 16:00:26
User entered '05 Aug 2020 12:00'	System	05 Aug 2020 16:00:26

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 5'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:34

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 6'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:27', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e6d62809-0376-4bb0-97ac-965020c39e1b'	System	07 Aug 2020 16:12:42
User entered 'Yes (Y)'	System	07 Aug 2020 16:12:42

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:34', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e6d62809-0376-4bb0-97ac-965020c39e1b' User entered '98.1'	System	07 Aug 2020 16:12:42

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:37', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e6d62809-0376-4bb0-97ac-965020c39e1b'	System	07 Aug 2020 16:12:42
User entered 'No (N)'	System	07 Aug 2020 16:12:42

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:39', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e6d62809-0376-4bb0-97ac-965020c39e1b'	System	07 Aug 2020 16:12:42
User entered '07 Aug 2020 12:12'	System	07 Aug 2020 16:12:42

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 7'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:51:48', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '67a70979-98b4-4d2e-8b20-f933fb7a4abb'	System	08 Aug 2020 16:52:05
User entered 'Yes (Y)'	System	08 Aug 2020 16:52:05

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:51:53', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '67a70979-98b4-4d2e-8b20-f933fb7a4abb' User entered '98.1'	System	08 Aug 2020 16:52:05
	System	08 Aug 2020 16:52:05

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:51:57', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '67a70979-98b4-4d2e-8b20-f933fb7a4abb'	System	08 Aug 2020 16:52:05
User entered 'No (N)'	System	08 Aug 2020 16:52:05

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '67a70979-98b4-4d2e-8b20-f933fb7a4abb' User entered '08 Aug 2020 12:52'	System	08 Aug 2020 16:52:05
	System	08 Aug 2020 16:52:05

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:27:42', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '46360fd2-232a-4efc-b89c-5b64e9c80f65'	System	02 Aug 2020 21:28:05
User entered 'None (1)'	System	02 Aug 2020 21:28:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:27:48', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '46360fd2-232a-4efc-b89c-5b64e9c80f65'	System	02 Aug 2020 21:28:05
User entered 'No (N)'	System	02 Aug 2020 21:28:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:27:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '46360fd2-232a-4efc-b89c-5b64e9c80f65'	System	02 Aug 2020 21:28:05
User entered 'No (N)'	System	02 Aug 2020 21:28:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:27:58', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '46360fd2-232a-4efc-b89c-5b64e9c80f65'	System	02 Aug 2020 21:28:05
User entered 'None (1)'	System	02 Aug 2020 21:28:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:02', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '46360fd2-232a-4efc-b89c-5b64e9c80f65'	System	02 Aug 2020 21:28:05
User entered '02 Aug 2020 17:28'	System	02 Aug 2020 21:28:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 17:08'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 19:38'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:45:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c775aa9d-aac8-4b7e-93c1-17f21225478e'	System	03 Aug 2020 02:46:24
User entered 'None (1)'	System	03 Aug 2020 02:46:24

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:45:58', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c775aa9d-aac8-4b7e-93c1-17f21225478e'	System	03 Aug 2020 02:46:24
User entered 'No (N)'	System	03 Aug 2020 02:46:24

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:46:05', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c775aa9d-aac8-4b7e-93c1-17f21225478e'	System	03 Aug 2020 02:46:24
User entered 'No (N)'	System	03 Aug 2020 02:46:24

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:46:16', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c775aa9d-aac8-4b7e-93c1-17f21225478e'	System	03 Aug 2020 02:46:24
User entered 'None (1)'	System	03 Aug 2020 02:46:24

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:46:22', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c775aa9d-aac8-4b7e-93c1-17f21225478e'	System	03 Aug 2020 02:46:24
User entered '02 Aug 2020 22:46'	System	03 Aug 2020 02:46:24

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 20:33'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 2'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:08', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '65745532-3c6d-4c4e-b44f-1d89bfdfac8'	System	04 Aug 2020 13:15:33
User entered 'None (1)'	System	04 Aug 2020 13:15:33

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '65745532-3c6d-4c4e-b44f-1d89bfdfac8'	System	04 Aug 2020 13:15:33
User entered 'No (N)'	System	04 Aug 2020 13:15:33

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:17', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '65745532-3c6d-4c4e-b44f-1d89bfdfac8'	System	04 Aug 2020 13:15:33
User entered 'No (N)'	System	04 Aug 2020 13:15:33

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:22', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '65745532-3c6d-4c4e-b44f-1d89bfdfac8'	System	04 Aug 2020 13:15:33
User entered 'None (1)'	System	04 Aug 2020 13:15:33

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:30', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '65745532-3c6d-4c4e-b44f-1d89bfdfac8'	System	04 Aug 2020 13:15:33
User entered '04 Aug 2020 09:15'	System	04 Aug 2020 13:15:33

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 3'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:10:51', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2ac7dc31-b59f-46ee-bcc1-1193ecb5de54'	System	04 Aug 2020 16:11:04
User entered 'None (1)'	System	04 Aug 2020 16:11:04

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:10:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2ac7dc31-b59f-46ee-bcc1-1193ecb5de54'	System	04 Aug 2020 16:11:04
User entered 'No (N)'	System	04 Aug 2020 16:11:04

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:10:57', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2ac7dc31-b59f-46ee-bcc1-1193ecb5de54'	System	04 Aug 2020 16:11:04
User entered 'No (N)'	System	04 Aug 2020 16:11:04

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:10:59', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2ac7dc31-b59f-46ee-bcc1-1193ecb5de54'	System	04 Aug 2020 16:11:04
User entered 'None (1)'	System	04 Aug 2020 16:11:04

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:01', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2ac7dc31-b59f-46ee-bcc1-1193ecb5de54'	System	04 Aug 2020 16:11:04
User entered '04 Aug 2020 12:11'	System	04 Aug 2020 16:11:04

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 4'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:30', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '6a68122a-27da-43eb-8b7e-4b8cdb255834'	System	05 Aug 2020 16:00:42
User entered 'None (1)'	System	05 Aug 2020 16:00:42

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:32', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '6a68122a-27da-43eb-8b7e-4b8cdb255834'	System	05 Aug 2020 16:00:42
User entered 'No (N)'	System	05 Aug 2020 16:00:42

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:34', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '6a68122a-27da-43eb-8b7e-4b8cdb255834'	System	05 Aug 2020 16:00:42
User entered 'No (N)'	System	05 Aug 2020 16:00:42

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:38', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '6a68122a-27da-43eb-8b7e-4b8cdb255834'	System	05 Aug 2020 16:00:42
User entered 'None (1)'	System	05 Aug 2020 16:00:42

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:40', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '6a68122a-27da-43eb-8b7e-4b8cdb255834'	System	05 Aug 2020 16:00:42
User entered '05 Aug 2020 12:00'	System	05 Aug 2020 16:00:42

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 5'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 6'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:49', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e1986a1a-e32d-4470-9e34-c0d6b735ba24'	System	07 Aug 2020 16:13:02
User entered 'None (1)'	System	07 Aug 2020 16:13:02

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e1986a1a-e32d-4470-9e34-c0d6b735ba24'	System	07 Aug 2020 16:13:02
User entered 'No (N)'	System	07 Aug 2020 16:13:02

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:53', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e1986a1a-e32d-4470-9e34-c0d6b735ba24'	System	07 Aug 2020 16:13:02
User entered 'No (N)'	System	07 Aug 2020 16:13:02

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:57', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e1986a1a-e32d-4470-9e34-c0d6b735ba24'	System	07 Aug 2020 16:13:02
User entered 'None (1)'	System	07 Aug 2020 16:13:02

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:59', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e1986a1a-e32d-4470-9e34-c0d6b735ba24'	System	07 Aug 2020 16:13:02
User entered '07 Aug 2020 12:12'	System	07 Aug 2020 16:13:02

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 7'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:05', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '742f6e79-0df4-4333-9ec6-f21f2a529cce'	System	08 Aug 2020 16:52:16
User entered 'None (1)'	System	08 Aug 2020 16:52:16

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:08', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '742f6e79-0df4-4333-9ec6-f21f2a529cce'	System	08 Aug 2020 16:52:16
User entered 'No (N)'	System	08 Aug 2020 16:52:16

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:10', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '742f6e79-0df4-4333-9ec6-f21f2a529cce'	System	08 Aug 2020 16:52:16
User entered 'No (N)'	System	08 Aug 2020 16:52:16

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:12', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '742f6e79-0df4-4333-9ec6-f21f2a529cce'	System	08 Aug 2020 16:52:16
User entered 'None (1)'	System	08 Aug 2020 16:52:16

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:14', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '742f6e79-0df4-4333-9ec6-f21f2a529cce'	System	08 Aug 2020 16:52:16
User entered '08 Aug 2020 12:52'	System	08 Aug 2020 16:52:16

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:10', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '39c139b7-7844-432e-8ff6-863ce077b1b5'	System	02 Aug 2020 21:28:35
User entered 'None (0)'	System	02 Aug 2020 21:28:35

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '39c139b7-7844-432e-8ff6-863ce077b1b5'	System	02 Aug 2020 21:28:35
User entered 'None (0)'	System	02 Aug 2020 21:28:35

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:16', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '39c139b7-7844-432e-8ff6-863ce077b1b5'	System	02 Aug 2020 21:28:35
User entered 'None (0)'	System	02 Aug 2020 21:28:35

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '39c139b7-7844-432e-8ff6-863ce077b1b5'	System	02 Aug 2020 21:28:35
User entered 'None (0)'	System	02 Aug 2020 21:28:35

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:22', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '39c139b7-7844-432e-8ff6-863ce077b1b5'	System	02 Aug 2020 21:28:35
User entered 'None (0)'	System	02 Aug 2020 21:28:35

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:25', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '39c139b7-7844-432e-8ff6-863ce077b1b5'	System	02 Aug 2020 21:28:35
User entered 'None (0)'	System	02 Aug 2020 21:28:35

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '39c139b7-7844-432e-8ff6-863ce077b1b5'	System	02 Aug 2020 21:28:35
User entered 'No (N)'	System	02 Aug 2020 21:28:35

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:32', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '39c139b7-7844-432e-8ff6-863ce077b1b5'	System	02 Aug 2020 21:28:35
User entered '02 Aug 2020 17:28'	System	02 Aug 2020 21:28:35

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 17:08'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 19:38'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:46:32', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ed1a2803-4633-4214-b9c3-7fed5cf93c6d'	System	03 Aug 2020 02:47:16
User entered 'None (0)'	System	03 Aug 2020 02:47:16

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:46:36', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ed1a2803-4633-4214-b9c3-7fed5cf93c6d'	System	03 Aug 2020 02:47:16
User entered 'None (0)'	System	03 Aug 2020 02:47:16

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:46:39', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ed1a2803-4633-4214-b9c3-7fed5cf93c6d'	System	03 Aug 2020 02:47:16
User entered 'None (0)'	System	03 Aug 2020 02:47:16

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:46:46', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ed1a2803-4633-4214-b9c3-7fed5cf93c6d'	System	03 Aug 2020 02:47:16
User entered 'None (0)'	System	03 Aug 2020 02:47:16

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:46:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ed1a2803-4633-4214-b9c3-7fed5cf93c6d'	System	03 Aug 2020 02:47:16
User entered 'None (0)'	System	03 Aug 2020 02:47:16

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:47:02', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ed1a2803-4633-4214-b9c3-7fed5cf93c6d'	System	03 Aug 2020 02:47:16
User entered 'None (0)'	System	03 Aug 2020 02:47:16

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:47:10', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ed1a2803-4633-4214-b9c3-7fed5cf93c6d'	System	03 Aug 2020 02:47:16
User entered 'No (N)'	System	03 Aug 2020 02:47:16

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:47:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ed1a2803-4633-4214-b9c3-7fed5cf93c6d'	System	03 Aug 2020 02:47:16
User entered '02 Aug 2020 22:47'	System	03 Aug 2020 02:47:16

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 20:33'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 2'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:40', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '280a6c06-f25f-4aa8-a3d2-2d0d231e2de7'	System	04 Aug 2020 13:16:14
User entered 'None (0)'	System	04 Aug 2020 13:16:14

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:45', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '280a6c06-f25f-4aa8-a3d2-2d0d231e2de7'	System	04 Aug 2020 13:16:14
User entered 'None (0)'	System	04 Aug 2020 13:16:14

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:50', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '280a6c06-f25f-4aa8-a3d2-2d0d231e2de7'	System	04 Aug 2020 13:16:14
User entered 'None (0)'	System	04 Aug 2020 13:16:14

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '280a6c06-f25f-4aa8-a3d2-2d0d231e2de7'	System	04 Aug 2020 13:16:14
User entered 'None (0)'	System	04 Aug 2020 13:16:14

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:57', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '280a6c06-f25f-4aa8-a3d2-2d0d231e2de7'	System	04 Aug 2020 13:16:14
User entered 'None (0)'	System	04 Aug 2020 13:16:14

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:16:01', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '280a6c06-f25f-4aa8-a3d2-2d0d231e2de7'	System	04 Aug 2020 13:16:14
User entered 'None (0)'	System	04 Aug 2020 13:16:14

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:16:08', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '280a6c06-f25f-4aa8-a3d2-2d0d231e2de7'	System	04 Aug 2020 13:16:14
User entered 'No (N)'	System	04 Aug 2020 13:16:14

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:16:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '280a6c06-f25f-4aa8-a3d2-2d0d231e2de7'	System	04 Aug 2020 13:16:14
User entered '04 Aug 2020 09:16'	System	04 Aug 2020 13:16:14

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 3'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:06', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '16b7353c-2571-4327-9003-62c1adc4ef84'	System	04 Aug 2020 16:11:29
User entered 'None (0)'	System	04 Aug 2020 16:11:29

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:09', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '16b7353c-2571-4327-9003-62c1adc4ef84'	System	04 Aug 2020 16:11:29
User entered 'None (0)'	System	04 Aug 2020 16:11:29

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:11', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '16b7353c-2571-4327-9003-62c1adc4ef84'	System	04 Aug 2020 16:11:29
User entered 'None (0)'	System	04 Aug 2020 16:11:29

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:14', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '16b7353c-2571-4327-9003-62c1adc4ef84'	System	04 Aug 2020 16:11:29
User entered 'None (0)'	System	04 Aug 2020 16:11:29

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:17', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '16b7353c-2571-4327-9003-62c1adc4ef84'	System	04 Aug 2020 16:11:29
User entered 'None (0)'	System	04 Aug 2020 16:11:29

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:20', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '16b7353c-2571-4327-9003-62c1adc4ef84'	System	04 Aug 2020 16:11:29
User entered 'None (0)'	System	04 Aug 2020 16:11:29

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:23', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '16b7353c-2571-4327-9003-62c1adc4ef84'	System	04 Aug 2020 16:11:29
User entered 'No (N)'	System	04 Aug 2020 16:11:29

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:27', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '16b7353c-2571-4327-9003-62c1adc4ef84'	System	04 Aug 2020 16:11:29
User entered '04 Aug 2020 12:11'	System	04 Aug 2020 16:11:29

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 4'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:46', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '68359bb7-7512-4ce3-b184-2aae3c724b13'	System	05 Aug 2020 16:01:02
User entered 'None (0)'	System	05 Aug 2020 16:01:02

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:48', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '68359bb7-7512-4ce3-b184-2aae3c724b13'	System	05 Aug 2020 16:01:02
User entered 'None (0)'	System	05 Aug 2020 16:01:02

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:50', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '68359bb7-7512-4ce3-b184-2aae3c724b13'	System	05 Aug 2020 16:01:02
User entered 'None (0)'	System	05 Aug 2020 16:01:02

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '68359bb7-7512-4ce3-b184-2aae3c724b13'	System	05 Aug 2020 16:01:02
User entered 'None (0)'	System	05 Aug 2020 16:01:02

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:53', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '68359bb7-7512-4ce3-b184-2aae3c724b13'	System	05 Aug 2020 16:01:02
User entered 'None (0)'	System	05 Aug 2020 16:01:02

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:55', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '68359bb7-7512-4ce3-b184-2aae3c724b13'	System	05 Aug 2020 16:01:02
User entered 'None (0)'	System	05 Aug 2020 16:01:02

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:58', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '68359bb7-7512-4ce3-b184-2aae3c724b13'	System	05 Aug 2020 16:01:02
User entered 'No (N)'	System	05 Aug 2020 16:01:02

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:01:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '68359bb7-7512-4ce3-b184-2aae3c724b13'	System	05 Aug 2020 16:01:02
User entered '05 Aug 2020 12:01'	System	05 Aug 2020 16:01:02

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 5'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 6'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:13:03', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '514af771-c625-4b3d-ba51-efa9fb5d1c23'	System	07 Aug 2020 16:13:25
User entered 'None (0)'	System	07 Aug 2020 16:13:25

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:13:05', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '514af771-c625-4b3d-ba51-efa9fb5d1c23'	System	07 Aug 2020 16:13:25
User entered 'None (0)'	System	07 Aug 2020 16:13:25

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:13:07', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '514af771-c625-4b3d-ba51-efa9fb5d1c23'	System	07 Aug 2020 16:13:25
User entered 'None (0)'	System	07 Aug 2020 16:13:25

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:13:08', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '514af771-c625-4b3d-ba51-efa9fb5d1c23'	System	07 Aug 2020 16:13:25
User entered 'None (0)'	System	07 Aug 2020 16:13:25

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:13:10', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '514af771-c625-4b3d-ba51-efa9fb5d1c23'	System	07 Aug 2020 16:13:25
User entered 'None (0)'	System	07 Aug 2020 16:13:25

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:13:12', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '514af771-c625-4b3d-ba51-efa9fb5d1c23'	System	07 Aug 2020 16:13:25
User entered 'None (0)'	System	07 Aug 2020 16:13:25

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:13:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '514af771-c625-4b3d-ba51-efa9fb5d1c23'	System	07 Aug 2020 16:13:25
User entered 'No (N)'	System	07 Aug 2020 16:13:25

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:13:22', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '514af771-c625-4b3d-ba51-efa9fb5d1c23'	System	07 Aug 2020 16:13:25
User entered '07 Aug 2020 12:13'	System	07 Aug 2020 16:13:25

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 7'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:18', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e8488040-74d0-4d6a-8a40-3efd011925af'	System	08 Aug 2020 16:52:46
User entered 'None (0)'	System	08 Aug 2020 16:52:46

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:21', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e8488040-74d0-4d6a-8a40-3efd011925af'	System	08 Aug 2020 16:52:46
User entered 'None (0)'	System	08 Aug 2020 16:52:46

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:23', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e8488040-74d0-4d6a-8a40-3efd011925af'	System	08 Aug 2020 16:52:46
User entered 'None (0)'	System	08 Aug 2020 16:52:46

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:24', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e8488040-74d0-4d6a-8a40-3efd011925af' User entered 'None (0)'	System	08 Aug 2020 16:52:46
	System	08 Aug 2020 16:52:46

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:26', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e8488040-74d0-4d6a-8a40-3efd011925af'	System	08 Aug 2020 16:52:46
User entered 'None (0)'	System	08 Aug 2020 16:52:46

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:28', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e8488040-74d0-4d6a-8a40-3efd011925af'	System	08 Aug 2020 16:52:46
User entered 'None (0)'	System	08 Aug 2020 16:52:46

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:35', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e8488040-74d0-4d6a-8a40-3efd011925af'	System	08 Aug 2020 16:52:46
User entered 'No (N)'	System	08 Aug 2020 16:52:46

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:42', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e8488040-74d0-4d6a-8a40-3efd011925af' User entered '08 Aug 2020 12:52'	System	08 Aug 2020 16:52:46
	System	08 Aug 2020 16:52:46

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 17:41:53

US3402194

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '9 Aug 2020'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 17:41:53

US3402194

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 17:41:53

US3402194

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 17:41:53

US3402194

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 17:41:59

US3402194

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 17:41:59

US3402194

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 15:24:08

US3402194

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 15:24:08

US3402194

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 15:24:08

US3402194

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 15:24:08

US3402194

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 15:24:14

US3402194

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 15:24:14

US3402194

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	24 Aug 2020 18:24:45
	(b) (4)	

US3402194

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	24 Aug 2020 18:24:45

US3402194

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4)	24 Aug 2020 18:24:45
	(b) (4)	

US3402194

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	24 Aug 2020 18:24:45
	(b) (4)	

US3402194

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	24 Aug 2020 18:24:54

US3402194

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 18:24:54

US3402194

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:27:49

US3402194

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:27:49

US3402194

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:27:49

US3402194

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	03 Sep 2020 12:27:49

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '15:07'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 15:07'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.1' C	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '88'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '18'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '16:32'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 16:32'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.0' C	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '96'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '18'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:09

US3402194

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:34

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:09

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '15:46'	(b) (4), (b) (6)	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 15:46'	System	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:21

US3402194

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Sample dated 02Sep2020 is recorded under Visit2 Day29 visit in EDC, however a sample is reported under UNSCHEDULED visit dated 02Sep2020 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 10:59:27
Query 'Per GCL Lab Reconciliation: Sample dated 02Sep2020 is recorded under Visit2 Day29 visit in EDC, however a sample is reported under UNSCHEDULED visit dated 02Sep2020 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Dates are correct as is will correct with PPD' (Site from DM).	Jennifer Molstead (b) (4)	10 Nov 2020 21:31:50
User opened query 'Per GCL Lab Reconciliation: Sample dated 02Sep2020 is recorded under Visit2 Day29 visit in EDC, however a sample is reported under UNSCHEDULED visit dated 02Sep2020 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 21:22:08
User entered '2 Sep 2020'	Traci Hull (b) (4)	03 Sep 2020 12:29:21

US3402194

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '15:32'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:21

US3402194

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 15:32'	System	03 Sep 2020 12:29:21

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:24:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab recon: Swab: Sample collection date 02-SEP-2020 is recorded under Visit 2 Day 29; however, corresponding swab sample is missing in PPD portal Kindly confirm if swab sample was collected on 02-SEP-2020 for Visit 2 Day 29 to be updated in PPD portal.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 12:20:24
Query 'Per GCL Lab recon: Swab: Sample collection date 02-SEP-2020 is recorded under Visit 2 Day 29; however, corresponding swab sample is missing in PPD portal Kindly confirm if swab sample was collected on 02-SEP-2020 for Visit 2 Day 29 to be updated in PPD portal.' answered with 'Correct as is' (Site from DM).	Jennifer Molstead (b) (4)	19 Nov 2020 12:09:31
User opened query 'Per GCL Lab recon: Swab: Sample collection date 02-SEP-2020 is recorded under Visit 2 Day 29; however, corresponding swab sample is missing in PPD portal Kindly confirm if swab sample was collected on 02-SEP-2020 for Visit 2 Day 29 to be updated in PPD portal.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:59:57
User entered '2 Sep 2020'	Traci Hull (b) (4)	03 Sep 2020 12:29:35

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:24:34

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:35

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:24:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:35

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:24:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '15:36'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:35

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 15:36'	System	03 Sep 2020 12:29:35

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:34

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:35

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:35

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:35

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 12:29:35

US3402194

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:39

US3402194

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 12:29:39

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:30:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '85fbec54-c9e8-4f7d-a05e-b30b29bd8106'	System	02 Sep 2020 20:31:26
User entered 'Yes (Y)'	System	02 Sep 2020 20:31:26

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:31:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '85fbec54-c9e8-4f7d-a05e-b30b29bd8106'	System	02 Sep 2020 20:31:26
User entered '98.6'	System	02 Sep 2020 20:31:26

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:31:15', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '85fbec54-c9e8-4f7d-a05e-b30b29bd8106'	System	02 Sep 2020 20:31:26
User entered 'No (N)'	System	02 Sep 2020 20:31:26

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:31:25', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '85fbec54-c9e8-4f7d-a05e-b30b29bd8106'	System	02 Sep 2020 20:31:26
User entered '02 Sep 2020 16:31'	System	02 Sep 2020 20:31:26

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 16:06'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 18:36'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:01', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a0049254-43d5-4f53-ac4e-b8871fbc8b4b'	System	02 Sep 2020 23:37:21
User entered 'Yes (Y)'	System	02 Sep 2020 23:37:21

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:08', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a0049254-43d5-4f53-ac4e-b8871fbc8b4b' User entered '98.6'	System	02 Sep 2020 23:37:21

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:16', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a0049254-43d5-4f53-ac4e-b8871fbc8b4b'	System	02 Sep 2020 23:37:21
User entered 'No (N)'	System	02 Sep 2020 23:37:21

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a0049254-43d5-4f53-ac4e-b8871fbc8b4b'	System	02 Sep 2020 23:37:21
User entered '02 Sep 2020 19:37'	System	02 Sep 2020 23:37:21

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 19:31'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 2'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:31:41', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c5a49e68-da51-4b15-8310-bb99dc3e288d'	System	04 Sep 2020 14:32:09
User entered 'Yes (Y)'	System	04 Sep 2020 14:32:09

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:34

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:31:46', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c5a49e68-da51-4b15-8310-bb99dc3e288d'	System	04 Sep 2020 14:32:09
User entered '98.6'	System	04 Sep 2020 14:32:09

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:31:58', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c5a49e68-da51-4b15-8310-bb99dc3e288d'	System	04 Sep 2020 14:32:09
User entered 'No (N)'	System	04 Sep 2020 14:32:09

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:03', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c5a49e68-da51-4b15-8310-bb99dc3e288d'	System	04 Sep 2020 14:32:09
User entered '04 Sep 2020 10:32'	System	04 Sep 2020 14:32:09

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 3'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:02:48', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '60ca8057-751f-4300-98b8-6fe9008623c5'	System	05 Sep 2020 14:03:05
User entered 'Yes (Y)'	System	05 Sep 2020 14:03:05

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:02:53', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '60ca8057-751f-4300-98b8-6fe9008623c5'	System	05 Sep 2020 14:03:05
User entered '98.6'	System	05 Sep 2020 14:03:05

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:02:58', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '60ca8057-751f-4300-98b8-6fe9008623c5'	System	05 Sep 2020 14:03:05
User entered 'No (N)'	System	05 Sep 2020 14:03:05

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:01', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '60ca8057-751f-4300-98b8-6fe9008623c5'	System	05 Sep 2020 14:03:05
User entered '05 Sep 2020 10:03'	System	05 Sep 2020 14:03:05

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 4'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:21:59', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'bbd0c63b-ca9c-4fa2-869c-812263743967'	System	05 Sep 2020 16:22:15
User entered 'Yes (Y)'	System	05 Sep 2020 16:22:15

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:22:07', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'bbd0c63b-ca9c-4fa2-869c-812263743967'	System	05 Sep 2020 16:22:15
User entered '98.6'	System	05 Sep 2020 16:22:15

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:22:11', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'bbd0c63b-ca9c-4fa2-869c-812263743967'	System	05 Sep 2020 16:22:15
User entered 'No (N)'	System	05 Sep 2020 16:22:15

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:22:14', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'bbd0c63b-ca9c-4fa2-869c-812263743967'	System	05 Sep 2020 16:22:15
User entered '05 Sep 2020 12:22'	System	05 Sep 2020 16:22:15

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 5'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:32:53', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c250db33-d00e-4cd0-a761-3abcb08907c6'	System	06 Sep 2020 21:33:07
User entered 'Yes (Y)'	System	06 Sep 2020 21:33:07

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:32:58', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c250db33-d00e-4cd0-a761-3abcb08907c6'	System	06 Sep 2020 21:33:07
User entered '98.6'	System	06 Sep 2020 21:33:07

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:02', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c250db33-d00e-4cd0-a761-3abcb08907c6'	System	06 Sep 2020 21:33:07
User entered 'No (N)'	System	06 Sep 2020 21:33:07

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:04', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c250db33-d00e-4cd0-a761-3abcb08907c6'	System	06 Sep 2020 21:33:07
User entered '06 Sep 2020 17:33'	System	06 Sep 2020 21:33:07

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 6'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:31:55', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '48e7ca20-8cd9-4469-a6f6-9c7762f1d170'	System	08 Sep 2020 00:32:11
User entered 'Yes (Y)'	System	08 Sep 2020 00:32:11

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:34

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:02', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '48e7ca20-8cd9-4469-a6f6-9c7762f1d170'	System	08 Sep 2020 00:32:11
User entered '98.6'	System	08 Sep 2020 00:32:11

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:06', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '48e7ca20-8cd9-4469-a6f6-9c7762f1d170'	System	08 Sep 2020 00:32:11
User entered 'No (N)'	System	08 Sep 2020 00:32:11

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:08', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '48e7ca20-8cd9-4469-a6f6-9c7762f1d170'	System	08 Sep 2020 00:32:11
User entered '07 Sep 2020 20:32'	System	08 Sep 2020 00:32:11

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 7'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7312c248-5ded-4a80-964d-37f64b047db9'	System	08 Sep 2020 16:03:24
User entered 'Yes (Y)'	System	08 Sep 2020 16:03:24

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:24', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7312c248-5ded-4a80-964d-37f64b047db9'	System	08 Sep 2020 16:03:24
User entered '98.6'	System	08 Sep 2020 16:03:24

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:27', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7312c248-5ded-4a80-964d-37f64b047db9'	System	08 Sep 2020 16:03:24
User entered 'No (N)'	System	08 Sep 2020 16:03:24

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7312c248-5ded-4a80-964d-37f64b047db9'	System	08 Sep 2020 16:03:24
User entered '08 Sep 2020 12:02'	System	08 Sep 2020 16:03:24

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:31:53', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c567ee74-0d0d-4c5b-a73b-aa22b31248af'	System	02 Sep 2020 20:32:16
User entered 'None (1)'	System	02 Sep 2020 20:32:16

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:31:59', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c567ee74-0d0d-4c5b-a73b-aa22b31248af' User entered 'No (N)'	System	02 Sep 2020 20:32:16

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:03', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c567ee74-0d0d-4c5b-a73b-aa22b31248af' User entered 'No (N)'	System	02 Sep 2020 20:32:16

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:10', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c567ee74-0d0d-4c5b-a73b-aa22b31248af'	System	02 Sep 2020 20:32:16
User entered 'None (1)'	System	02 Sep 2020 20:32:16

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c567ee74-0d0d-4c5b-a73b-aa22b31248af' User entered '02 Sep 2020 16:32'	System	02 Sep 2020 20:32:16
	System	02 Sep 2020 20:32:16

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 16:06'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 18:36'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:24', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '36287c6e-8e12-4302-aa60-c8683192de42'	System	02 Sep 2020 23:37:44
User entered 'None (1)'	System	02 Sep 2020 23:37:44

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '36287c6e-8e12-4302-aa60-c8683192de42'	System	02 Sep 2020 23:37:44
User entered 'No (N)'	System	02 Sep 2020 23:37:44

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:33', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '36287c6e-8e12-4302-aa60-c8683192de42'	System	02 Sep 2020 23:37:44
User entered 'No (N)'	System	02 Sep 2020 23:37:44

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:38', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '36287c6e-8e12-4302-aa60-c8683192de42'	System	02 Sep 2020 23:37:44
User entered 'None (1)'	System	02 Sep 2020 23:37:44

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:41', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '36287c6e-8e12-4302-aa60-c8683192de42'	System	02 Sep 2020 23:37:44
User entered '02 Sep 2020 19:37'	System	02 Sep 2020 23:37:44

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 19:31'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 2'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '161ec10d-80c5-461c-843c-6a11853dfe85'	System	04 Sep 2020 14:32:32
User entered 'None (1)'	System	04 Sep 2020 14:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '161ec10d-80c5-461c-843c-6a11853dfe85'	System	04 Sep 2020 14:32:32
User entered 'No (N)'	System	04 Sep 2020 14:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:23', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '161ec10d-80c5-461c-843c-6a11853dfe85'	System	04 Sep 2020 14:32:32
User entered 'No (N)'	System	04 Sep 2020 14:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:25', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '161ec10d-80c5-461c-843c-6a11853dfe85'	System	04 Sep 2020 14:32:32
User entered 'None (1)'	System	04 Sep 2020 14:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:28', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '161ec10d-80c5-461c-843c-6a11853dfe85'	System	04 Sep 2020 14:32:32
User entered '04 Sep 2020 10:32'	System	04 Sep 2020 14:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 3'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:08', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2673107a-82b9-4cfe-a642-5ac41a2719c8'	System	05 Sep 2020 14:03:21
User entered 'None (1)'	System	05 Sep 2020 14:03:21

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:12', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2673107a-82b9-4cfe-a642-5ac41a2719c8'	System	05 Sep 2020 14:03:21
User entered 'No (N)'	System	05 Sep 2020 14:03:21

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:14', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2673107a-82b9-4cfe-a642-5ac41a2719c8'	System	05 Sep 2020 14:03:21
User entered 'No (N)'	System	05 Sep 2020 14:03:21

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:16', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2673107a-82b9-4cfe-a642-5ac41a2719c8'	System	05 Sep 2020 14:03:21
User entered 'None (1)'	System	05 Sep 2020 14:03:21

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:18', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2673107a-82b9-4cfe-a642-5ac41a2719c8'	System	05 Sep 2020 14:03:21
User entered '05 Sep 2020 10:03'	System	05 Sep 2020 14:03:21

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 4'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:22:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1e81075d-b92a-440a-98ad-6aadec187300'	System	05 Sep 2020 16:22:34
User entered 'None (1)'	System	05 Sep 2020 16:22:34

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:22:23', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1e81075d-b92a-440a-98ad-6aadec187300'	System	05 Sep 2020 16:22:34
User entered 'No (N)'	System	05 Sep 2020 16:22:34

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:22:25', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1e81075d-b92a-440a-98ad-6aadec187300'	System	05 Sep 2020 16:22:34
User entered 'No (N)'	System	05 Sep 2020 16:22:34

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:22:27', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1e81075d-b92a-440a-98ad-6aadec187300'	System	05 Sep 2020 16:22:34
User entered 'None (1)'	System	05 Sep 2020 16:22:34

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:22:31', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1e81075d-b92a-440a-98ad-6aadec187300' User entered '05 Sep 2020 12:22'	System	05 Sep 2020 16:22:34
	System	05 Sep 2020 16:22:34

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 5'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:11', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'debd0251-c14d-40a2-a546-a3e67aad0dd0'	System	06 Sep 2020 21:33:30
User entered 'None (1)'	System	06 Sep 2020 21:33:30

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:17', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'debd0251-c14d-40a2-a546-a3e67aad0dd0'	System	06 Sep 2020 21:33:30
User entered 'No (N)'	System	06 Sep 2020 21:33:30

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:20', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'debd0251-c14d-40a2-a546-a3e67aad0dd0' User entered 'No (N)'	System	06 Sep 2020 21:33:30

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:22', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'debd0251-c14d-40a2-a546-a3e67aad0dd0'	System	06 Sep 2020 21:33:30
User entered 'None (1)'	System	06 Sep 2020 21:33:30

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:26', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'debd0251-c14d-40a2-a546-a3e67aad0dd0'	System	06 Sep 2020 21:33:30
User entered '06 Sep 2020 17:33'	System	06 Sep 2020 21:33:30

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 6'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:14', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'eb7d98c3-30df-44f2-bd75-0ffeb9600dbc' User entered 'None (1)'	System	08 Sep 2020 00:32:32
	System	08 Sep 2020 00:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'eb7d98c3-30df-44f2-bd75-0ffeb9600dbc'	System	08 Sep 2020 00:32:32
User entered 'No (N)'	System	08 Sep 2020 00:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:21', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'eb7d98c3-30df-44f2-bd75-0ffeb9600dbc' User entered 'No (N)'	System	08 Sep 2020 00:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:24', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'eb7d98c3-30df-44f2-bd75-0ffeb9600dbc' User entered 'None (1)'	System	08 Sep 2020 00:32:32
	System	08 Sep 2020 00:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:27', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'eb7d98c3-30df-44f2-bd75-0ffeb9600dbc' User entered '07 Sep 2020 20:32'	System	08 Sep 2020 00:32:32
	System	08 Sep 2020 00:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 7'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:32', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'aedaf888-d09b-48e6-b9a5-4a43e908a991'	System	08 Sep 2020 16:03:32
User entered 'None (1)'	System	08 Sep 2020 16:03:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:35', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'aedaf888-d09b-48e6-b9a5-4a43e908a991'	System	08 Sep 2020 16:03:32
User entered 'No (N)'	System	08 Sep 2020 16:03:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:36', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'aedaf888-d09b-48e6-b9a5-4a43e908a991'	System	08 Sep 2020 16:03:32
User entered 'No (N)'	System	08 Sep 2020 16:03:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:38', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'aedaf888-d09b-48e6-b9a5-4a43e908a991'	System	08 Sep 2020 16:03:32
User entered 'None (1)'	System	08 Sep 2020 16:03:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:41', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'aedaf888-d09b-48e6-b9a5-4a43e908a991'	System	08 Sep 2020 16:03:32
User entered '08 Sep 2020 12:02'	System	08 Sep 2020 16:03:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:20', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7a5cbc2b-214f-46bc-9e00-0061dd4c5f7e'	System	02 Sep 2020 20:32:51
User entered 'None (0)'	System	02 Sep 2020 20:32:51

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:25', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7a5cbc2b-214f-46bc-9e00-0061dd4c5f7e'	System	02 Sep 2020 20:32:51
User entered 'None (0)'	System	02 Sep 2020 20:32:51

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7a5cbc2b-214f-46bc-9e00-0061dd4c5f7e'	System	02 Sep 2020 20:32:51
User entered 'None (0)'	System	02 Sep 2020 20:32:51

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:31', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7a5cbc2b-214f-46bc-9e00-0061dd4c5f7e' User entered 'None (0)'	System	02 Sep 2020 20:32:51
	System	02 Sep 2020 20:32:51

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:34', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7a5cbc2b-214f-46bc-9e00-0061dd4c5f7e'	System	02 Sep 2020 20:32:51
User entered 'None (0)'	System	02 Sep 2020 20:32:51

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:37', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7a5cbc2b-214f-46bc-9e00-0061dd4c5f7e'	System	02 Sep 2020 20:32:51
User entered 'None (0)'	System	02 Sep 2020 20:32:51

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:45', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7a5cbc2b-214f-46bc-9e00-0061dd4c5f7e'	System	02 Sep 2020 20:32:51
User entered 'No (N)'	System	02 Sep 2020 20:32:51

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:48', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7a5cbc2b-214f-46bc-9e00-0061dd4c5f7e'	System	02 Sep 2020 20:32:51
User entered '02 Sep 2020 16:32'	System	02 Sep 2020 20:32:51

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 16:06'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 18:36'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:46', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'df93d7fb-8bc4-4bb3-95b8-cda0e1b573e9'	System	02 Sep 2020 23:38:05
User entered 'None (0)'	System	02 Sep 2020 23:38:05

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:48', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'df93d7fb-8bc4-4bb3-95b8-cda0e1b573e9'	System	02 Sep 2020 23:38:05
User entered 'None (0)'	System	02 Sep 2020 23:38:05

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:50', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'df93d7fb-8bc4-4bb3-95b8-cda0e1b573e9'	System	02 Sep 2020 23:38:05
User entered 'None (0)'	System	02 Sep 2020 23:38:05

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'df93d7fb-8bc4-4bb3-95b8-cda0e1b573e9'	System	02 Sep 2020 23:38:05
User entered 'None (0)'	System	02 Sep 2020 23:38:05

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'df93d7fb-8bc4-4bb3-95b8-cda0e1b573e9'	System	02 Sep 2020 23:38:05
User entered 'None (0)'	System	02 Sep 2020 23:38:05

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:56', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'df93d7fb-8bc4-4bb3-95b8-cda0e1b573e9'	System	02 Sep 2020 23:38:05
User entered 'None (0)'	System	02 Sep 2020 23:38:05

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:38:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'df93d7fb-8bc4-4bb3-95b8-cda0e1b573e9'	System	02 Sep 2020 23:38:05
User entered 'No (N)'	System	02 Sep 2020 23:38:05

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:38:03', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'df93d7fb-8bc4-4bb3-95b8-cda0e1b573e9'	System	02 Sep 2020 23:38:05
User entered '02 Sep 2020 19:38'	System	02 Sep 2020 23:38:05

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 19:31'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 2'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:33', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1c77c699-4b3d-4cfb-94ce-cb2b09b7d5c3'	System	04 Sep 2020 14:32:56
User entered 'None (0)'	System	04 Sep 2020 14:32:56

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:35', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1c77c699-4b3d-4cfb-94ce-cb2b09b7d5c3'	System	04 Sep 2020 14:32:56
User entered 'None (0)'	System	04 Sep 2020 14:32:56

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:37', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1c77c699-4b3d-4cfb-94ce-cb2b09b7d5c3'	System	04 Sep 2020 14:32:56
User entered 'None (0)'	System	04 Sep 2020 14:32:56

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:40', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1c77c699-4b3d-4cfb-94ce-cb2b09b7d5c3'	System	04 Sep 2020 14:32:56
User entered 'None (0)'	System	04 Sep 2020 14:32:56

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:42', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1c77c699-4b3d-4cfb-94ce-cb2b09b7d5c3'	System	04 Sep 2020 14:32:56
User entered 'None (0)'	System	04 Sep 2020 14:32:56

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:44', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1c77c699-4b3d-4cfb-94ce-cb2b09b7d5c3'	System	04 Sep 2020 14:32:56
User entered 'None (0)'	System	04 Sep 2020 14:32:56

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1c77c699-4b3d-4cfb-94ce-cb2b09b7d5c3'	System	04 Sep 2020 14:32:56
User entered 'No (N)'	System	04 Sep 2020 14:32:56

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1c77c699-4b3d-4cfb-94ce-cb2b09b7d5c3'	System	04 Sep 2020 14:32:56
User entered '04 Sep 2020 10:32'	System	04 Sep 2020 14:32:56

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 3'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:22', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ad69710e-748f-432a-90cb-2be20845c71a'	System	05 Sep 2020 14:03:44
User entered 'None (0)'	System	05 Sep 2020 14:03:44

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:25', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ad69710e-748f-432a-90cb-2be20845c71a'	System	05 Sep 2020 14:03:44
User entered 'None (0)'	System	05 Sep 2020 14:03:44

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:27', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ad69710e-748f-432a-90cb-2be20845c71a'	System	05 Sep 2020 14:03:44
User entered 'None (0)'	System	05 Sep 2020 14:03:44

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ad69710e-748f-432a-90cb-2be20845c71a'	System	05 Sep 2020 14:03:44
User entered 'None (0)'	System	05 Sep 2020 14:03:44

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:31', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ad69710e-748f-432a-90cb-2be20845c71a'	System	05 Sep 2020 14:03:44
User entered 'None (0)'	System	05 Sep 2020 14:03:44

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:33', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ad69710e-748f-432a-90cb-2be20845c71a'	System	05 Sep 2020 14:03:44
User entered 'None (0)'	System	05 Sep 2020 14:03:44

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:40', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ad69710e-748f-432a-90cb-2be20845c71a'	System	05 Sep 2020 14:03:44
User entered 'No (N)'	System	05 Sep 2020 14:03:44

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:42', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ad69710e-748f-432a-90cb-2be20845c71a'	System	05 Sep 2020 14:03:44
User entered '05 Sep 2020 10:03'	System	05 Sep 2020 14:03:44

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 4'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T13:13:10', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '27f4db82-9c57-405d-a782-d9ac2404ee8b'	System	05 Sep 2020 17:13:27
User entered 'None (0)'	System	05 Sep 2020 17:13:27

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T13:13:12', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '27f4db82-9c57-405d-a782-d9ac2404ee8b'	System	05 Sep 2020 17:13:27
User entered 'None (0)'	System	05 Sep 2020 17:13:27

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T13:13:14', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '27f4db82-9c57-405d-a782-d9ac2404ee8b'	System	05 Sep 2020 17:13:27
User entered 'None (0)'	System	05 Sep 2020 17:13:27

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T13:13:17', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '27f4db82-9c57-405d-a782-d9ac2404ee8b' User entered 'None (0)'	System	05 Sep 2020 17:13:27
	System	05 Sep 2020 17:13:27

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T13:13:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '27f4db82-9c57-405d-a782-d9ac2404ee8b'	System	05 Sep 2020 17:13:27
User entered 'None (0)'	System	05 Sep 2020 17:13:27

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T13:13:21', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '27f4db82-9c57-405d-a782-d9ac2404ee8b'	System	05 Sep 2020 17:13:27
User entered 'None (0)'	System	05 Sep 2020 17:13:27

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T13:13:24', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '27f4db82-9c57-405d-a782-d9ac2404ee8b'	System	05 Sep 2020 17:13:27
User entered 'No (N)'	System	05 Sep 2020 17:13:27

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T13:13:26', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '27f4db82-9c57-405d-a782-d9ac2404ee8b'	System	05 Sep 2020 17:13:27
User entered '05 Sep 2020 13:13'	System	05 Sep 2020 17:13:27

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 5'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:36', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '50747a51-e9c0-47bf-b0b7-1a3dcabefe7'	System	06 Sep 2020 21:33:58
User entered 'None (0)'	System	06 Sep 2020 21:33:58

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:38', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '50747a51-e9c0-47bf-b0b7-1a3dcbabefe7'	System	06 Sep 2020 21:33:58
User entered 'None (0)'	System	06 Sep 2020 21:33:58

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:39', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '50747a51-e9c0-47bf-b0b7-1a3dcbabefe7'	System	06 Sep 2020 21:33:58
User entered 'None (0)'	System	06 Sep 2020 21:33:58

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:41', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '50747a51-e9c0-47bf-b0b7-1a3dcabafe7'	System	06 Sep 2020 21:33:58
User entered 'None (0)'	System	06 Sep 2020 21:33:58

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:44', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '50747a51-e9c0-47bf-b0b7-1a3dcabefe7'	System	06 Sep 2020 21:33:58
User entered 'None (0)'	System	06 Sep 2020 21:33:58

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:46', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '50747a51-e9c0-47bf-b0b7-1a3dcbabefe7'	System	06 Sep 2020 21:33:58
User entered 'None (0)'	System	06 Sep 2020 21:33:58

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '50747a51-e9c0-47bf-b0b7-1a3dcabafe7'	System	06 Sep 2020 21:33:58
User entered 'No (N)'	System	06 Sep 2020 21:33:58

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '50747a51-e9c0-47bf-b0b7-1a3dcbabefe7' User entered '06 Sep 2020 17:33'	System	06 Sep 2020 21:33:58
	System	06 Sep 2020 21:33:58

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 6'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:59', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '196fff97-ad94-4679-b8f9-46dfc6ad4bf3'	System	08 Sep 2020 00:33:40
User entered 'None (0)'	System	08 Sep 2020 00:33:40

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:33:03', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '196fff97-ad94-4679-b8f9-46dfc6ad4bf3'	System	08 Sep 2020 00:33:40
User entered 'None (0)'	System	08 Sep 2020 00:33:40

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:33:06', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '196fff97-ad94-4679-b8f9-46dfc6ad4bf3'	System	08 Sep 2020 00:33:40
User entered 'None (0)'	System	08 Sep 2020 00:33:40

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:33:09', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '196fff97-ad94-4679-b8f9-46dfc6ad4bf3' User entered 'None (0)'	System	08 Sep 2020 00:33:40
	System	08 Sep 2020 00:33:40

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:33:12', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '196fff97-ad94-4679-b8f9-46dfc6ad4bf3'	System	08 Sep 2020 00:33:40
User entered 'None (0)'	System	08 Sep 2020 00:33:40

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:33:17', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '196fff97-ad94-4679-b8f9-46dfc6ad4bf3'	System	08 Sep 2020 00:33:40
User entered 'None (0)'	System	08 Sep 2020 00:33:40

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:33:20', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '196fff97-ad94-4679-b8f9-46dfc6ad4bf3'	System	08 Sep 2020 00:33:40
User entered 'No (N)'	System	08 Sep 2020 00:33:40

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:33:37', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '196fff97-ad94-4679-b8f9-46dfc6ad4bf3'	System	08 Sep 2020 00:33:40
User entered '07 Sep 2020 20:33'	System	08 Sep 2020 00:33:40

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 7'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:44', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52efdf0e-c6e5-489a-9a2b-9ad55eb64736'	System	08 Sep 2020 16:03:49
User entered 'None (0)'	System	08 Sep 2020 16:03:49

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:47', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52efdf0e-c6e5-489a-9a2b-9ad55eb64736'	System	08 Sep 2020 16:03:49
User entered 'None (0)'	System	08 Sep 2020 16:03:49

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:48', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52efdf0e-c6e5-489a-9a2b-9ad55eb64736'	System	08 Sep 2020 16:03:49
User entered 'None (0)'	System	08 Sep 2020 16:03:49

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:50', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52efdf0e-c6e5-489a-9a2b-9ad55eb64736'	System	08 Sep 2020 16:03:49
User entered 'None (0)'	System	08 Sep 2020 16:03:49

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52efdf0e-c6e5-489a-9a2b-9ad55eb64736'	System	08 Sep 2020 16:03:49
User entered 'None (0)'	System	08 Sep 2020 16:03:49

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52efdf0e-c6e5-489a-9a2b-9ad55eb64736'	System	08 Sep 2020 16:03:49
User entered 'None (0)'	System	08 Sep 2020 16:03:49

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:56', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52efdf0e-c6e5-489a-9a2b-9ad55eb64736'	System	08 Sep 2020 16:03:49
User entered 'No (N)'	System	08 Sep 2020 16:03:49

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:59', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52efdf0e-c6e5-489a-9a2b-9ad55eb64736'	System	08 Sep 2020 16:03:49
User entered '08 Sep 2020 12:02'	System	08 Sep 2020 16:03:49

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	09 Sep 2020 13:49:13

US3402194

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '9 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	09 Sep 2020 13:49:13

US3402194

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	09 Sep 2020 13:49:13

US3402194

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	09 Sep 2020 13:49:13

US3402194

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	09 Sep 2020 13:49:17

US3402194

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 13:49:17

US3402194

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Sep 2020 11:22:58

US3402194

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Traci Hull (b) (4) (b) (4)	17 Sep 2020 11:22:58

US3402194

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	17 Sep 2020 11:22:58

US3402194

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Sep 2020 11:22:58

US3402194

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Sep 2020 11:22:48

US3402194

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 11:22:48

US3402194

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 13:57:41

US3402194

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 13:57:41

US3402194

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 13:57:41

US3402194

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 13:57:41

US3402194

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 13:57:45

US3402194

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 13:57:45

US3402194

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:47:48

US3402194

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:47:48

US3402194

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:47:48

US3402194

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	30 Sep 2020 18:47:48

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '14:11'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 14:11'	System	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '84'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '14'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '127'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '61'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:24

US3402194

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:34

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:24

US3402194

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:37

US3402194

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30SEP2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Visit 3 Day57 Visit with date 02OCT2020 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 06:44:11
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30SEP2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Visit 3 Day57 Visit with date 02OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you' answered with 'DATA WAS UPDATED BY THE LAB.' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	26 Oct 2020 12:17:41
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30SEP2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Visit 3 Day57 Visit with date 02OCT2020 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)	23 Oct 2020 12:04:02
User entered '30 Sep 2020'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:37

US3402194

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:16'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:37

US3402194

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 14:16'	System	30 Sep 2020 18:51:37

US3402194

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:47:39

US3402194

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 18:47:39

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 64'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-02T00:04:50', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '624c8698-2ac9-4442-8a3d-5d37c950a9d0'	System	02 Oct 2020 04:05:19
User entered 'No (N)'	System	02 Oct 2020 04:05:19

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-02T00:05:02', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '624c8698-2ac9-4442-8a3d-5d37c950a9d0'	System	02 Oct 2020 04:05:19
User entered 'No (N)'	System	02 Oct 2020 04:05:19

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-02T00:05:16', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '624c8698-2ac9-4442-8a3d-5d37c950a9d0'	System	02 Oct 2020 04:05:19
User entered '02 Oct 2020 00:05:16'	System	02 Oct 2020 04:05:19

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '02 Oct 2020 00:01'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '06 Oct 2020 23:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 71'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-09T00:01:36', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '42d1677c-2f81-4109-98e8-42512721066d'	System	09 Oct 2020 04:02:06
User entered 'No (N)'	System	09 Oct 2020 04:02:06

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-09T00:01:43', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '42d1677c-2f81-4109-98e8-42512721066d'	System	09 Oct 2020 04:02:06
User entered 'No (N)'	System	09 Oct 2020 04:02:06

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-09T00:02:01', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '42d1677c-2f81-4109-98e8-42512721066d'	System	09 Oct 2020 04:02:06
User entered '09 Oct 2020 00:02:01'	System	09 Oct 2020 04:02:06

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '09 Oct 2020 00:01'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '13 Oct 2020 23:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 78'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-16T00:01:36', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c9d982f7-7801-403a-8c55-6068ed6fe959'	System	16 Oct 2020 04:01:50
User entered 'No (N)'	System	16 Oct 2020 04:01:50

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-16T00:01:43', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c9d982f7-7801-403a-8c55-6068ed6fe959'	System	16 Oct 2020 04:01:50
User entered 'No (N)'	System	16 Oct 2020 04:01:50

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-16T00:01:48', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c9d982f7-7801-403a-8c55-6068ed6fe959'	System	16 Oct 2020 04:01:50
User entered '16 Oct 2020 00:01:48'	System	16 Oct 2020 04:01:50

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '16 Oct 2020 00:01'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '20 Oct 2020 23:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 92'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-03T12:31:30', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a6442a7f-4354-40fd-8f5b-a814e9d6044b'	System	03 Nov 2020 17:32:07
User entered 'No (N)'	System	03 Nov 2020 17:32:07

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-03T12:31:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a6442a7f-4354-40fd-8f5b-a814e9d6044b'	System	03 Nov 2020 17:32:07
User entered 'No (N)'	System	03 Nov 2020 17:32:07

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-03T12:32:04', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a6442a7f-4354-40fd-8f5b-a814e9d6044b' User entered '03 Nov 2020 12:32:04'	System	03 Nov 2020 17:32:07
	System	03 Nov 2020 17:32:07

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '30 Oct 2020 00:01'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '03 Nov 2020 23:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 99'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-06T00:01:51', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ddb9f50b-5bc1-4d0e-a518-9904b94be4b4' User entered 'No (N)'	System	06 Nov 2020 05:02:15
	System	06 Nov 2020 05:02:15

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-06T00:02:08', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ddb9f50b-5bc1-4d0e-a518-9904b94be4b4' User entered 'No (N)'	System	06 Nov 2020 05:02:15
	System	06 Nov 2020 05:02:15

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-06T00:02:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ddb9f50b-5bc1-4d0e-a518-9904b94be4b4' User entered '06 Nov 2020 00:02:13'	System	06 Nov 2020 05:02:15
	System	06 Nov 2020 05:02:15

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '06 Nov 2020 00:01'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '10 Nov 2020 23:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 106'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T08:59:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered 'Yes (Y)'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T08:59:55', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered 'Yes (Y)'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:00:24', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be'	System	13 Nov 2020 14:02:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:00:47', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered 'Yes (Y)'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '1'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '1'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '1'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '1'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:40', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be'	System	13 Nov 2020 14:02:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:56', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered 'No (N)'	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:02:17', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '13 Nov 2020 09:02:17'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '13 Nov 2020 00:01'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '17 Nov 2020 23:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '29 Sep 2020 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '03 Oct 2020 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '06 Oct 2020 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '10 Oct 2020 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '13 Oct 2020 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '17 Oct 2020 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '20 Oct 2020 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '24 Oct 2020 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '27 Oct 2020 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '31 Oct 2020 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '03 Nov 2020 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '07 Nov 2020 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '10 Nov 2020 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '14 Nov 2020 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '17 Nov 2020 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '21 Nov 2020 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '24 Nov 2020 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '28 Nov 2020 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '01 Dec 2020 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '05 Dec 2020 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '08 Dec 2020 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '12 Dec 2020 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '15 Dec 2020 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '19 Dec 2020 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '22 Dec 2020 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '26 Dec 2020 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '29 Dec 2020 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '02 Jan 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '05 Jan 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '09 Jan 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '12 Jan 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '16 Jan 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '19 Jan 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '23 Jan 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '26 Jan 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '30 Jan 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '02 Feb 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '06 Feb 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '09 Feb 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '13 Feb 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '16 Feb 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '20 Feb 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '23 Feb 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '27 Feb 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '02 Mar 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '06 Mar 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '09 Mar 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '13 Mar 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '16 Mar 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '20 Mar 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '23 Mar 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '27 Mar 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '30 Mar 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '03 Apr 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '06 Apr 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '10 Apr 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '13 Apr 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '17 Apr 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '20 Apr 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '24 Apr 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '27 Apr 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '01 May 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '04 May 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '08 May 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '11 May 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '15 May 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '18 May 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '22 May 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '25 May 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '29 May 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '01 Jun 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '05 Jun 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '08 Jun 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '12 Jun 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '15 Jun 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '19 Jun 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '22 Jun 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '26 Jun 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '29 Jun 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '03 Jul 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '06 Jul 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '10 Jul 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '13 Jul 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '17 Jul 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '20 Jul 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '24 Jul 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '27 Jul 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '31 Jul 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '03 Aug 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '07 Aug 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '10 Aug 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '14 Aug 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '17 Aug 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '21 Aug 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '24 Aug 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '28 Aug 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '31 Aug 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '04 Sep 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '07 Sep 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '11 Sep 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '14 Sep 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '18 Sep 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '21 Sep 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '25 Sep 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '28 Sep 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '02 Oct 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '05 Oct 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '09 Oct 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '12 Oct 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '16 Oct 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '19 Oct 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '23 Oct 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '26 Oct 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '30 Oct 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '02 Nov 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '06 Nov 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '09 Nov 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '13 Nov 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '16 Nov 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '20 Nov 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '23 Nov 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '27 Nov 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '30 Nov 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '04 Dec 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '07 Dec 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '11 Dec 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '14 Dec 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '18 Dec 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '21 Dec 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '25 Dec 2021 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '28 Dec 2021 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '01 Jan 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '04 Jan 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '08 Jan 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '11 Jan 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '15 Jan 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '18 Jan 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '22 Jan 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '25 Jan 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '29 Jan 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '01 Feb 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '05 Feb 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '08 Feb 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '12 Feb 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '15 Feb 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '19 Feb 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '22 Feb 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '26 Feb 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '01 Mar 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '05 Mar 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '08 Mar 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '12 Mar 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '15 Mar 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '19 Mar 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '22 Mar 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '26 Mar 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '29 Mar 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '02 Apr 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '05 Apr 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '09 Apr 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '12 Apr 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '16 Apr 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '19 Apr 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '23 Apr 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '26 Apr 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '30 Apr 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '03 May 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '07 May 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '10 May 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '14 May 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '17 May 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '21 May 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '24 May 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '28 May 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '31 May 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '04 Jun 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '07 Jun 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '11 Jun 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '14 Jun 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '18 Jun 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '21 Jun 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '25 Jun 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '28 Jun 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '02 Jul 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '05 Jul 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '09 Jul 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '12 Jul 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '16 Jul 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '19 Jul 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '23 Jul 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '26 Jul 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '30 Jul 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '02 Aug 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '06 Aug 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '09 Aug 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '13 Aug 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '16 Aug 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '20 Aug 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '23 Aug 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '27 Aug 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '30 Aug 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '03 Sep 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '06 Sep 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '10 Sep 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '13 Sep 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '17 Sep 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '20 Sep 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '24 Sep 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '27 Sep 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '01 Oct 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '04 Oct 2022 00:01'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '08 Oct 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 17:49:57

US3402194

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '26 Oct 2020'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 17:49:57

US3402194

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 17:49:57

US3402194

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Oct 2020 17:49:57

US3402194

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 17:49:47

US3402194

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 17:49:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:24:34

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:03:13
User entered '13 Nov 2020'	Traci Hull (b) (4)	16 Nov 2020 12:58:36
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:24:34

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:03:13
User entered '11:30'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:58:36

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:24:34

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020 11:30'	System	16 Nov 2020 12:58:36

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:24:34

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:03:13
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:58:36

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:24:34

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:03:13
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:58:36

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User closed query 'Please reconcile as AE start date = 03Nov2020. Per CCGs and training provided to all sites symptom log Day 1 = day subject first experienced symptoms. Please add 03Nov2020 - 12Nov2020 beginning on line 7 and then update symptom day # only on lines 1-6.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 04:26:29
Query 'Please reconcile as AE start date = 03Nov2020. Per CCGs and training provided to all sites symptom log Day 1 = day subject first experienced symptoms. Please add 03Nov2020 - 12Nov2020 beginning on line 7 and then update symptom day # only on lines 1-6.' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:51
User entered 'Day 9 (Day 9)' reason for change: New Information	(b) (4)	19 Nov 2020 20:34:27
User opened query 'Please reconcile as AE start date = 03Nov2020. Per CCGs and training provided to all sites symptom log Day 1 = day subject first experienced symptoms. Please add 03Nov2020 - 12Nov2020 beginning on line 7 and then update symptom day # only on lines 1-6.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 13:36:08
User entered 'Day 1 (Day 1)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '14 Nov 2020' reason for change: New Information	Jennifer Molstead (b) (4)	20 Nov 2020 19:44:15
User entered '12 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:22:57
User entered '13 Nov 2020'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4)	16 Nov 2020 13:02:12
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '99' reason for change: New Information	Jennifer Molstead (b) (4)	20 Nov 2020 19:44:15
User entered '96' reason for change: New Information	Traci Hull (b) (4)	16 Nov 2020 13:04:35
User entered empty.	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	16 Nov 2020 13:04:35
User entered empty.	System	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '99.0' F reason for change: Data Entry Error	Jennifer Molstead (b) (4)	20 Nov 2020 19:44:15
User entered '99.3' F	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Moderate (Moderate)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Not Done (Not Done)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Not Done (Not Done)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Moderate (Moderate)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Not Done (Not Done)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Not Done (Not Done)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Moderate (Moderate)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Not Done (Not Done)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Not Done (Not Done)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Not Done (Not Done)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Not Done (Not Done)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:34:27
User entered 'Day 2 (Day 2)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '15 Nov 2020' reason for change: New Information	Jennifer Molstead (b) (4)	20 Nov 2020 19:44:15
User entered '13 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:22:57
User entered '14 Nov 2020'	Traci Hull (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '94' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	20 Nov 2020 19:44:15
User entered '99'	Traci Hull (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '99.0' F	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:31:35
User closed query 'Per source, started 15-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:31:33
Query 'Per source, started 15-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:20:10
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:19:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	25 Nov 2020 03:19:27
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User opened query 'Per source, started 15-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:32:28
User entered 'None (None)'	Traci Hull (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
User closed query 'Per source, started 15-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:31:41
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:31:40
Query 'Per source, started 15-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:20:21
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:19:58
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	25 Nov 2020 03:19:58
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User opened query 'Per source, started 15-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:31:45
User entered 'None (None)'	Traci Hull (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4)	16 Nov 2020 13:02:59
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
User opened query 'Per source - diarrhea is listed as mild. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:33:02
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
User closed query 'Per source, started 15-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:32:22
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:31:51
Query 'Per source, started 15-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:20:33
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:19:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	25 Nov 2020 03:19:27
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User opened query 'Per source, started 15-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:31:12
User entered 'None (None)'	Traci Hull (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:34:27
User entered 'Day 3 (Day 3)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '16 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:22:57
User entered '15 Nov 2020'	Traci Hull (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '83' reason for change: New Information	Jennifer Molstead (b) (4)	20 Nov 2020 19:40:57
User entered '99'	Traci Hull (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '99.0' F	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:34:27
User entered 'Day 4 (Day 4)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '17 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:22:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:25:42
User entered '16 Nov 2020' reason for change: Data Entry Error	System	19 Nov 2020 13:25:42
User opened query 'Data is required. Please complete.' (Site from System).	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	(b) (4)	
	System	19 Nov 2020 12:10:26
	Traci Hull (b) (4)	19 Nov 2020 12:10:26
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '92' reason for change: New Information	Jennifer Molstead (b) (4)	20 Nov 2020 19:40:57
User entered '83' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 13:25:42
User entered empty.	System	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '98.9' F reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:34:27
User entered 'Day 5 (Day 5)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '18 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:22:57
User entered '17 Nov 2020'	Traci Hull (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4)	19 Nov 2020 12:13:30
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '94' reason for change: New Information	Jennifer Molstead (b) (4)	20 Nov 2020 19:40:57
User entered '92'	Traci Hull (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '97.3' F	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4)	19 Nov 2020 12:13:30
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4)	19 Nov 2020 12:13:30
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:34:27
User entered 'Day 6 (Day 6)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '19 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:22:57
User entered '18 Nov 2020'	Traci Hull (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4)	19 Nov 2020 12:14:01
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '94'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:10:41
User entered '06 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:19:57
User entered '05 Nov 2020'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:10:39
User entered '0'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:10:37
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 20:37:02

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:10:35
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:10:19
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:35:04
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:03
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:48
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:34
User entered 'None (None)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:34
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:10:28
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:09:37
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:09:35
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:09:34
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:09:32
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:09:30
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:09:29
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:09:18
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:09:16
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:09:15
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:09:13
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:09:22
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:34:58
User closed query 'Per source, started 10-NOV-2020. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:34:57
Query 'Per source, started 10-NOV-2020. Please review and update entries.' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:58
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:34
User entered 'None (None)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:34
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:08:13
User opened query 'Per source, started 10-NOV-2020. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:07:40
Query 'Per source, started 10-NOV-2020' canceled (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:07:22
User opened query 'Per source, started 10-NOV-2020' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:07:08
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:34:55
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:34:53
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:05
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:34
User entered 'None (None)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:34
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:08:11
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:08:05
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:34:52
	(b) (4), (b) (6)	
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:34:50
	(b) (4), (b) (6)	
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:12
	(b) (4)	
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:34
	(b) (4)	
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:34
	(b) (4)	
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:08:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:08:09
	(b) (4), (b) (6)	
User entered 'Moderate (Moderate)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:23
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:08:27
User entered 'None (None)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:23
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:10:51
User entered '07 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:19:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:47:19
User entered '06 Nov 2020' reason for change: New Information	System	19 Nov 2020 20:47:19
User opened query 'Data is required. Please complete.' (Site from System).	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	(b) (4)	
	System	19 Nov 2020 20:39:40
	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:10:53
User entered '0'	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:10:54
User entered missing code ND - Not Done; reason for change New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 20:47:19
User entered empty.	System	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:10:56
User entered missing code ND - Not Done; reason for change New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:11:15
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:35:20
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:18
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:24:02
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:49
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:49
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:13:47
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:11:19
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:11:21
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:11:25
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:11:49
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:11:53
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:11:55
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:11:57
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:12:00
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:12:07
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:12:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:12:30
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:35:25
	(b) (4), (b) (6)	
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:23
	(b) (4), (b) (6)	
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:24:17
DataPoint Un-verified.	(b) (4)	
	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:49
	(b) (4)	
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:49
	(b) (4)	
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:12:58
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:12:32
	(b) (4), (b) (6)	
User entered 'Moderate (Moderate)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:35:28
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:26
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:24:24
	(b) (4)	
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:49
	(b) (4)	
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:49
	(b) (4)	
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:13:13
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:13:01
User entered 'Moderate (Moderate)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:35:31
	(b) (4), (b) (6)	
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:30
	(b) (4), (b) (6)	
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:24:31
	(b) (4)	
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:49
	(b) (4)	
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:49
	(b) (4)	
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:13:27
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:13:03
	(b) (4), (b) (6)	
User entered 'Moderate (Moderate)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' canceled (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:13:38
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:13:35
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:13:05
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:17:52
User entered '08 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:19:57
User entered '07 Nov 2020'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:17:49
User entered '0'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:17:47
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 20:47:19

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:17:45
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:17:30
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:35:44
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:42
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:33
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:23
User entered 'None (None)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:23
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:17:43
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:17:41
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:17:19
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:17:17
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:17:15
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:17:10
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:17:08
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:17:04
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:17:03
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:17:01
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:16:59
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:16:57
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:35:49
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:47
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:47
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:23
User entered 'None (None)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:23
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:16:52
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:15:29
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:35:52
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:50
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:54
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:23
User entered 'None (None)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:23
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:16:45
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:15:55
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:35:54
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:53
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:26:01
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:23
User entered 'None (None)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:23
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:16:43
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:16:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:19:56
User entered '09 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:19:57
User entered '08 Nov 2020'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:01
User entered '0'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:04
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:05
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:09
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:36:06
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:36:04
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:26:59
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:26:50
User entered 'None (None)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	25 Nov 2020 03:26:50
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:13
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:18:53
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:18
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:20
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:22
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:24
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:26
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:30
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:32
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:33
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:35
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:37
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:36:12
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:36:11
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:27:08
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:26:50
User entered 'None (None)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	25 Nov 2020 03:26:50
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:39
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:19:10
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:36:15
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:36:14
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:27:16
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:26:50
User entered 'None (None)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	25 Nov 2020 03:26:50
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:42
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:19:36
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:36:18
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:36:17
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:27:23
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:26:50
User entered 'None (None)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	25 Nov 2020 03:26:50
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:44
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:19:38
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:48
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '10 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:21:05
User entered '09 Nov 2020'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 20:53:46

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:53:46
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '11 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:21:05
User entered '10 Nov 2020'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 20:54:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:54:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '12 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:21:05
User entered '11 Nov 2020'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 20:55:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:55:35
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '13 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:21:05
User entered '12 Nov 2020'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '96' reason for change: New Information	Jennifer Molstead (b) (4)	20 Nov 2020 19:44:15
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '99.3' F reason for change: New Information	Jennifer Molstead (b) (4)	20 Nov 2020 19:44:15
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '20 Nov 2020'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4)	23 Nov 2020 12:20:28
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '94'	Traci Hull (b) (4)	23 Nov 2020 12:20:28
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4)	23 Nov 2020 12:20:28
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '21 Nov 2020'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '94'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '98.2' F	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4)	23 Nov 2020 14:44:29
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '22 Nov 2020'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '92'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4)	23 Nov 2020 14:44:56
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 18 (Day 18)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '23 Nov 2020'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '92'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4)	24 Nov 2020 12:20:06
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4)	24 Nov 2020 12:20:06
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:24:34

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:24:34

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:03:28
User entered '13 Nov 2020'	Jennifer Molstead (b) (4)	17 Nov 2020 14:13:33
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:24:34

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:03:28
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	17 Nov 2020 14:13:33
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:24:34

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:03:28
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)	23 Nov 2020 11:43:55
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 'updated' (Site from System).	Jennifer Molstead (b) (4)	19 Nov 2020 12:05:29
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	17 Nov 2020 14:13:33
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	17 Nov 2020 14:13:33

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:24:34

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:03:28
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "17-NOV-2020" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "13-NOV-2020" for Illness Visit Day 1. Kindly review the collection date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:50:54
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "17-NOV-2020" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "13-NOV-2020" for Illness Visit Day 1. Kindly review the collection date and update as appropriate, else clarify.' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4)	19 Nov 2020 12:07:46
User entered '13 Nov 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	19 Nov 2020 12:07:39
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "17-NOV-2020" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "13-NOV-2020" for Illness Visit Day 1. Kindly review the collection date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 12:02:07
User entered '17 Nov 2020'	Jennifer Molstead (b) (4)	17 Nov 2020 14:13:33

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:24:34

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:03:28
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jennifer Molstead (b) (4)	17 Nov 2020 14:13:33

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:24:34

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:03:28
User entered empty.	Jennifer Molstead (b) (4)	17 Nov 2020 14:13:33
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:24:34

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:03:28
User entered 'No (N)'	Jennifer Molstead (b) (4)	17 Nov 2020 14:13:33
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:24:34

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:03:28
User entered empty.	Jennifer Molstead (b) (4)	17 Nov 2020 14:13:33
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:24:34

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:03:28
User entered empty.	Jennifer Molstead (b) (4)	17 Nov 2020 14:13:33
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:24:34

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 14:13:33

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

Did the subject have Respiratory Rates $\geq$ 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

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)	25 Nov 2020 00:04:04
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User closed query 'Please verify date as symptom log notes 16NOV2020' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:44:47
Query 'Please verify date as symptom log notes 16NOV2020' answered with 'UPDATED' (Site from CRA).	Jennifer Molstead (b) (4)	23 Nov 2020 16:50:22
User entered '16 Nov 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	23 Nov 2020 16:50:14
User opened query 'Please verify date as symptom log notes 16NOV2020' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:03:30
User entered '16 Oct 2020'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered '83' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	20 Nov 2020 19:39:30
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered '16 Oct 2020'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:24:34

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57
	(b) (4)	

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:24:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:24:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:24:34

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User entered '15 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:24:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:24:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:28:36
User entered 'No (N)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	25 Nov 2020 03:28:36
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User entered 'Yes (Y)' reason for change: Per Query Resolution	Traci Hull (b) (4)	19 Nov 2020 12:09:26
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:58:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 12:58:03
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4)	16 Nov 2020 12:58:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:57:40
User entered empty.	Traci Hull (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:24:34

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per source, subject did not take saliva kit to hospital. Please review and update entries.' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:28:47
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:28:36
User entered empty; reason for change Per Query Resolution	Jennifer Molstead (b) (4)	25 Nov 2020 03:28:36
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User opened query 'Per source, subject did not take saliva kit to hospital. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:02:27
User entered '17 Nov 2020' reason for change: Per Query Resolution	Traci Hull (b) (4)	19 Nov 2020 12:09:26
User entered empty.	Traci Hull (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:24:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:24:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:58:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 12:58:03
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4)	16 Nov 2020 12:58:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:57:40
User entered empty.	Traci Hull (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:24:34

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:24:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:24:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:58:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 12:58:03
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4)	16 Nov 2020 12:58:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:57:40
User entered empty.	Traci Hull (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:24:34

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:24:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:24:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:58:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 12:58:03
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4)	16 Nov 2020 12:58:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:57:40
User entered empty.	Traci Hull (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:24:34

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:24:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:24:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:58:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 12:58:03
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4)	16 Nov 2020 12:58:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:57:40
User entered empty.	Traci Hull (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:24:34

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:24:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:24:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:58:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 12:58:03
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4)	16 Nov 2020 12:58:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:57:40
User entered empty.	Traci Hull (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:24:34

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:53:53

US3402194

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:34
User entered '13 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:53:53

US3402194

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:34
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:53:53

US3402194

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:34

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	16 Nov 2020 12:53:53

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered '13 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered '11:37'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '13 Nov 2020 11:37'	System	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Height (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:55:43
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Nov 2020 13:33:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	16 Nov 2020 13:33:47
Comment added 'correct as is.'	(b) (4)	
	Traci Hull (b) (4)	16 Nov 2020 12:56:10
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Nov 2020 12:55:33
User entered 'N/D' (non-conformant).	Traci Hull (b) (4)	16 Nov 2020 12:55:33
	(b) (4)	
DataPoint set to visible.	System	16 Nov 2020 12:53:53

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:55:43
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Nov 2020 13:33:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	16 Nov 2020 13:33:47
Comment added 'correct as is'.	(b) (4)	
	Traci Hull (b) (4)	16 Nov 2020 12:56:26
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Nov 2020 12:55:33
User entered 'N/D' (non-conformant).	Traci Hull (b) (4)	16 Nov 2020 12:55:33
	(b) (4)	
DataPoint set to visible.	System	16 Nov 2020 12:53:53

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered '99.3' F	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered '87'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered '14'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered '107'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered '65'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:55:54
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:56:52

US3402194

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:34

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:55:54
User entered '13 Nov 2020'	Traci Hull (b) (4)	16 Nov 2020 12:56:52
	(b) (4)	

US3402194

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:24:34

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:56:00
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:23

US3402194

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:24:34

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:56:00
User entered '13 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:23

US3402194

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:24:34

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:19
User entered 'Yes (Y)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	17 Nov 2020 14:13:52
User entered 'No (N)'	Traci Hull (b) (4)	03 Aug 2020 14:42:16

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:06
User entered 'USA-US059-2020-mRNA-1273-P301000018'	System	18 Nov 2020 15:53:59
User entered 'New'	(b) (4), (b) (6)	18 Nov 2020 15:53:59

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User closed query 'Please consider updating term to COVID-19' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:37:13
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)	23 Nov 2020 20:13:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:13:02
Data point term sent to Coder	System	23 Nov 2020 20:12:00
Query 'Please consider updating term to COVID-19' answered with 'UPDATED' (Site from CRA).	Traci Hull (b) (4) (b) (4)	23 Nov 2020 20:11:51
Coding entries removed.	Traci Hull (b) (4) (b) (4)	23 Nov 2020 20:11:43
User entered 'COVID-19' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	23 Nov 2020 20:11:43
User opened query 'Please consider updating term to COVID-19' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 18:13:44
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)	17 Nov 2020 14:17:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 14:17:47
Data point term sent to Coder	System	17 Nov 2020 14:16:28
User entered 'Sars Covid-19'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'No (N)'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '05 Nov 2020' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:31:57
User entered '03 Nov 2020'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered empty.	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 14:16:23

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered empty.	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered empty.	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6) System	20 Nov 2020 19:55:58 17 Nov 2020 14:16:23

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '0'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '0'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 13:18:50
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'PATIENT STILL IN HOSPITAL' (Site from System).	Traci Hull (b) (4) (b) (4)	23 Nov 2020 20:13:48
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	23 Nov 2020 20:13:24
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 04:07:23
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'not available at this time' (Site from System).	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:51
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	17 Nov 2020 14:16:23
User entered '1'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '16 Nov 2020'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 15:16:04
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'STILL IN HOSPITAL' (Site from Safety).	Traci Hull (b) (4)	23 Nov 2020 20:13:01
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:56:25
User entered empty.	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User closed query 'Per CDM RQ: Response noted. However, if subject is currently not admitted to ICU, please update field. If ICU admission changes, please update field appropriately. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:48:18
Query 'Per CDM RQ: Response noted. However, if subject is currently not admitted to ICU, please update field. If ICU admission changes, please update field appropriately. ' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4)	23 Nov 2020 20:13:57
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4)	23 Nov 2020 20:13:24
User opened query 'Per CDM RQ: Response noted. However, if subject is currently not admitted to ICU, please update field. If ICU admission changes, please update field appropriately. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:45:38
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 13:44:53
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'not available at this time' (Site from System).	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:53
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	17 Nov 2020 14:16:23
User entered 'Unknown (UNK)'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered empty.	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '0'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '0'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '0'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '0' reason for change: New Information	Traci Hull (b) (4)	23 Nov 2020 20:14:50
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	17 Nov 2020 16:51:19
User entered '1' reason for change: Data Entry Error	System	17 Nov 2020 16:51:19
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	Tammy Kohn (b) (4)	17 Nov 2020 16:51:19
User entered '0'	(b) (4)	17 Nov 2020 14:16:23
	System	17 Nov 2020 14:16:23
	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '1' reason for change: New Information	Traci Hull (b) (4)	23 Nov 2020 20:14:50
User entered '0'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '0'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Per Query Resolution	Traci Hull (b) (4)	23 Nov 2020 20:14:50
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:56:16
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered empty.	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:57:28
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:57:03
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:56:50
User entered 'Subject admitted 16Nov2020 no records available yet.'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 14:16:23

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 14:16:23

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 14:16:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:24:34

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:40:55
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:42:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: ADMELOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 14:57:06
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 Aug 2020 14:57:06
Data point term sent to Coder	System	03 Aug 2020 14:47:23
Data point term sent to Coder	System	03 Aug 2020 14:45:22
User entered 'admelog u-100'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'type 1 diabetes'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User closed query 'Per DM CLR: Please review and provide the dose range (e.g., 5-10 IU) instead of stating 'SLIDING SCALE'. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:41:09
Query 'Per DM CLR: Please review and provide the dose range (e.g., 5-10 IU) instead of stating 'SLIDING SCALE'. Update as appropriate. ' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4) (b) (4)	08 Oct 2020 14:33:33
User entered '100' reason for change: New Information	Traci Hull (b) (4) (b) (4)	08 Oct 2020 14:33:25
User opened query 'Per DM CLR: Please review and provide the dose range (e.g., 5-10 IU) instead of stating 'SLIDING SCALE'. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 11:02:28
User entered 'sliding scale'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Other (OTHER)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'UNITS' reason for change: New Information	Traci Hull (b) (4)	08 Oct 2020 14:33:25
User entered 'sliding scale'	Traci Hull (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 14:46:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 14:46:44
User entered 'three times daily (TID)' reason for change: Data Entry Error	Traci Hull (b) (4)	03 Aug 2020 14:46:44
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 14:45:19
User entered empty.	Traci Hull (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 14:46:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 14:46:44
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Traci Hull (b) (4)	03 Aug 2020 14:46:44
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 14:45:19
User entered empty.	Traci Hull (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 00:06:43
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4)	03 Aug 2020 14:46:36
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 14:45:19
User entered 'un UNK 1979'	Traci Hull (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 Aug 2020 14:46:44
User entered empty.	System	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 14:46:44
User entered empty.	System	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 14:46:44
User entered empty.	System	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 19:37:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 19:37:48
Data point term sent to Coder Coding entries removed.	System Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:36:29 18 Nov 2020 19:36:10
User entered 'BRILINTA' reason for change: Per Query Resolution	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:36:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:09:04
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 Aug 2020 21:09:04
Data point term sent to Coder User entered 'brlinta'	System Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:23 03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'peripheral vascular disease'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '90'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4)	03 Aug 2020 14:46:00
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 00:06:47
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4)	03 Aug 2020 14:46:09
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 14:46:00
User entered 'un UNK 2018'	Traci Hull (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4)	03 Aug 2020 14:46:00
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 14:57:07
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 Aug 2020 14:57:07
Data point term sent to Coder	System	03 Aug 2020 14:48:24
User entered 'atorvastatin'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'coronary artery disease'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '20'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 00:06:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4)	03 Aug 2020 14:48:51
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 14:47:40
User entered 'un May 2017'	Traci Hull (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:32:14
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 Aug 2020 14:32:14
Data point term sent to Coder	System	03 Aug 2020 14:49:24
User entered 'lisinopril'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'coronary artery disease'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '2.5'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	03 Aug 2020 14:48:27
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 00:06:56
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4)	03 Aug 2020 14:48:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 14:48:27
User entered 'un May 2017'	Traci Hull (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 23:00:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 23:00:49
Data point term sent to Coder	System	18 Nov 2020 18:58:23
User entered 'albuterol'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4)	18 Nov 2020 18:57:50
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '90'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'ug (ug)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'as needed (PRN)'	Abigail Wine (b) (4)	18 Nov 2020 18:57:50
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4)	18 Nov 2020 18:57:50
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:04:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:04:55
Data point term sent to Coder	System	18 Nov 2020 19:03:34
User entered 'dexamethasone'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4)	18 Nov 2020 19:03:24
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '6'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'once daily (QD)'	Abigail Wine (b) (4)	18 Nov 2020 19:03:24
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Intravenous (INTRAVENOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 19:05:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 19:05:48
Data point term sent to Coder	System	18 Nov 2020 19:04:35
User entered 'acetaminophen'	Abigail Wine (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4)	18 Nov 2020 19:04:26
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '650'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'every 4 hours'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Oral (ORAL)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4)	18 Nov 2020 19:04:26
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 04:04:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	19 Nov 2020 04:04:59
Data point term sent to Coder	System	18 Nov 2020 19:05:37
User entered 'dextrose'	Abigail Wine (b) (4)	18 Nov 2020 19:05:09
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4)	18 Nov 2020 19:05:09
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4)	18 Nov 2020 19:05:09
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '50'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mL (mL)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'once (ONCE)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Intravenous (INTRAVENOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4)	18 Nov 2020 19:05:09
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:09:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:09:59
Data point term sent to Coder	System	18 Nov 2020 19:06:41
User entered 'furosemide'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4)	18 Nov 2020 19:06:12
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '20'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'once daily (QD)'	Abigail Wine (b) (4)	18 Nov 2020 19:06:12
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Oral (ORAL)'	Abigail Wine (b) (4)	18 Nov 2020 19:06:12
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4)	18 Nov 2020 19:06:12
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4)	18 Nov 2020 19:06:12
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 23:01:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 23:01:49
Data point term sent to Coder	System	18 Nov 2020 19:24:12
User entered 'ascorbic acid'	Abigail Wine (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4)	18 Nov 2020 19:23:43
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '1000'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'other (OTHER)'	Abigail Wine (b) (4)	18 Nov 2020 19:23:43
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'every 8 hours'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Intravenous (INTRAVENOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '17 Nov 2020'	Abigail Wine (b) (4)	18 Nov 2020 19:23:43
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:23:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 19:23:49
User entered 'No (N)' reason for change: Per Query Resolution	Abigail Wine (b) (4)	18 Nov 2020 19:23:49
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:23:43
User entered empty.	Abigail Wine (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 23:02:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 23:02:49
Data point term sent to Coder	System	18 Nov 2020 19:25:17
User entered 'aspirin'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '81'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'once daily (QD)'	Abigail Wine (b) (4)	18 Nov 2020 19:24:35
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Oral (ORAL)'	Abigail Wine (b) (4)	18 Nov 2020 19:24:35
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4)	18 Nov 2020 19:24:35
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: CARBOHYDRATES, PRODUCT: GLUCOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:25:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:25:53
Data point term sent to Coder	System	18 Nov 2020 19:26:17
User entered 'glucose chewable tablet'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4)	18 Nov 2020 19:25:24
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '12'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'g (g)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'as needed (PRN)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Oral (ORAL)'	Abigail Wine (b) (4)	18 Nov 2020 19:25:24
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:11:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:11:01
Data point term sent to Coder	System	18 Nov 2020 19:27:18
User entered 'heparin'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4)	18 Nov 2020 19:27:06
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '40'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'units/kg'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'other (OTHER)'	Abigail Wine (b) (4)	18 Nov 2020 19:27:06
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'every 6 hours'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Intravenous (INTRAVENOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTS YNOM: DEXTROSE WATER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:49:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	18 Nov 2020 19:29:20
User entered 'D5W'	Abigail Wine (b) (4)	18 Nov 2020 19:28:47
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4)	18 Nov 2020 19:28:47
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0-24'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'units/kg/hour'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'every 6 hours'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Intravenous (INTRAVENOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:57:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:57:02
Data point term sent to Coder	System	18 Nov 2020 19:32:23
User entered 'insulin glargine'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'diabetes type 1'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '30'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'units'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'three times daily (TID)'	Abigail Wine (b) (4)	18 Nov 2020 19:31:25
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Subcutaneous (SUBCUTANEOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4)	18 Nov 2020 19:31:25
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4)	18 Nov 2020 19:31:25
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:57:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:57:02
Data point term sent to Coder	System	18 Nov 2020 19:32:25
User entered 'insulin lispro'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'diabetes type 1'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '2-6'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'units'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'three times daily (TID)'	Abigail Wine (b) (4)	18 Nov 2020 19:32:18
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Subcutaneous (SUBCUTANEOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:41:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:41:53
Data point term sent to Coder	System	18 Nov 2020 19:33:26
User entered 'remdesivir'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4)	18 Nov 2020 19:33:23
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '100'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'once daily (QD)'	Abigail Wine (b) (4)	18 Nov 2020 19:33:23
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Intravenous (INTRAVENOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '18 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4)	18 Nov 2020 19:33:23
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:39:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:39:56
Data point term sent to Coder	System	18 Nov 2020 19:34:28
User entered 'sodium chloride infusion'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4)	18 Nov 2020 19:34:24
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0.9'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '%'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'as needed (PRN)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Intravenous (INTRAVENOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4)	18 Nov 2020 19:34:24
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: THIAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:52:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:52:59
Data point term sent to Coder	System	18 Nov 2020 19:35:29
User entered 'thiamine'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4)	18 Nov 2020 19:35:02
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '100'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'other (OTHER)'	Abigail Wine (b) (4)	18 Nov 2020 19:35:02
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'every 8 hours'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Intravenous (INTRAVENOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '17 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4)	18 Nov 2020 19:35:02
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:41:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:41:59
Data point term sent to Coder	System	19 Nov 2020 13:31:12
User entered 'Oxygen'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 13:30:29
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Sars Covid 19'	Jennifer Molstead (b) (4)	19 Nov 2020 13:30:29
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '6'	Jennifer Molstead (b) (4)	19 Nov 2020 13:30:29
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4)	19 Nov 2020 13:30:29
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Liters'	Jennifer Molstead (b) (4)	19 Nov 2020 13:30:29
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'other (OTHER)'	Jennifer Molstead (b) (4)	19 Nov 2020 13:30:29
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'continuous'	Jennifer Molstead (b) (4)	19 Nov 2020 13:30:29
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 13:30:29
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Jennifer Molstead (b) (4)	19 Nov 2020 13:30:29
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Jennifer Molstead (b) (4)	19 Nov 2020 13:30:29
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	19 Nov 2020 13:30:29
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 13:30:29
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Jennifer Molstead (b) (4)	19 Nov 2020 13:30:29
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:24:34

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:40:49
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 20:38:35

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'USA-US059-2020-MRNA-1273-P301000018'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Frank'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Eder'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '1290 Upper Front Street'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Binghamton'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'NY'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '13901'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:03:03
User entered 'US'	System	18 Nov 2020 15:54:28

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 15:25:57
User entered '2'	System	20 Nov 2020 15:03:14
User entered '1'	System	18 Nov 2020 15:54:28

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'USA-US059-2020-MRNA-1273-P301000018'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Frank'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Eder'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '1290 Upper Front Street'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Binghamton'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'NY'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '13901'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:03:03
User entered 'US'	System	18 Nov 2020 15:54:28

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 15:25:57
User entered '2'	System	20 Nov 2020 15:03:14
User entered '1'	System	18 Nov 2020 15:54:28

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:24:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
User entered '18/Nov/2020 15:54'	System	18 Nov 2020 15:54:28

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:24:34

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)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:03:03
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 15:54:28

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'USA-US059-2020-MRNA-1273-P301000018'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Frank'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Eder'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '1290 Upper Front Street'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Binghamton'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'NY'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '13901'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:03:03
User entered 'US'	System	18 Nov 2020 15:54:28

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 15:25:57
User entered '2'	System	20 Nov 2020 15:03:14
User entered '1'	System	18 Nov 2020 15:54:28

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:24:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
User entered '20/Nov/2020 15:03'	System	20 Nov 2020 15:03:14

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:24:34

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)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:25:41
User entered '1'	(b) (4), (b) (6)	20 Nov 2020 15:03:14

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'USA-US059-2020-MRNA-1273-P301000018'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Frank'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Eder'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '1290 Upper Front Street'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Binghamton'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'NY'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '13901'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:03:03
User entered 'US'	System	18 Nov 2020 15:54:28

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 15:25:57
User entered '2'	System	20 Nov 2020 15:03:14
User entered '1'	System	18 Nov 2020 15:54:28

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:24:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
User entered '24/Nov/2020 15:25'	System	24 Nov 2020 15:25:57

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:24:34

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)	25 Nov 2020 00:29:00
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 15:25:57